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United States District Court,
D. Minnesota.

MEDTRONIC, INC., Plaintiff,
v.
BOSTON SCIENTIFIC CORPORATION, and SciMed Life Systems, Inc., Defendants.

Civil No. 99-1035 (RHK/FLN).

Aug. 8, 2002.

Named Expert: Dr. John C. Muskivitch, Dr. Kaushik Bhattacharya, Goldscheider, Dr. Lagoudas

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MEMORANDUM OPINION AND ORDER

RICHARD H. KYLE, District Judge.

***1** This is a patent case in which Plaintiff Medtronic, Inc. alleges that Defendants Boston Scientific Corporation and SciMed Life Systems, Inc., (collectively "BSC") have, through their manufacture and sale of a product called the RADIUSTM stent system, infringed multiple claims in each of two patents relating to the use of shape memory alloys in medical devices (hereinafter "the Jervis patents" or "the patents-in-suit"). For their part, BSC denies that the RADIUSTM stent system infringes any of the claims of the patents-in-suit. BSC also is pursuing counterclaims alleging that the Jervis patents are invalid either under 35 U.S.C. § 102 or because a combination of several prior art references render them obvious under 35 U.S.C. § 103.

Before the Court are the parties' Motions in Limine. Each party has brought six motions. Several relate to the admissibility of testimony under Federal Rules of Evidence 701, 702, and 703 and the Supreme Court's decision in Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) and its progeny. Others involve the damages component of Medtronic's infringement case. Finally, there are motions to exclude evidence not fitting either of the previous two categories. The Court begins with the motions relating to expert testimony

I. Motions in Limine Relating to Expert Testimony

A. General principles

The admissibility of expert testimony and the qualifications of a witness to testify as an expert are preliminary questions that the district court must determine. Fed.R.Evid. 104(a). The proponent of the proposed expert testimony bears the burden of demonstrating by a preponderance of the evidence that it is admissible. See Daubert, 509 U.S. at 592 & n. 10; Bourjaily v. U.S., 483 U.S. 171, 175-76, 107 S.Ct. 2775, 97 L.Ed.2d 144 (1987); Lauzon v. Senco Prods. Inc., 270 F.3d 681, 686 (8th Cir.2001).

Effective December 1, 2000, Rule 702 was amended to add language consistent with the holdings from a line of Supreme Court opinions regarding expert testimony that began with Daubert. [FN1] As amended, Rule 702 provides that

> FN1. At the time this action was commenced, Rule 702 provided that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise." Fed.R.Evid. 702 (2000).

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by

> knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts.

Fed.R.Evid. 702 (2001) (emphasis added).

Under both Daubert and the amended Rule 702, the trial judge is charged with a "gatekeeper function," the objective of which is to ensure the reliability and relevance of the expert testimony admitted into evidence. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 149, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). The court ensures the relevance of proposed expert testimony by evaluating whether the opinions offered are sufficiently tied to the facts of the case, see Daubert, 509 U.S. at 591, and ensures the reliability of such testimony by considering a number of non-exclusive factors, such as "(1) whether the theory or technique can be (and has been) tested, (2) whether the theory has been subjected to peer review and publication, (3) the known or potential rate of error, and (4) whether the theory has been generally accepted." Peitzmeier v. Hennessy Indus., Inc., 97 F.3d 293, 297 (8th Cir.1996) (quoting Daubert, 509 U.S. at 593-94). Other factors pertinent to assessing the reliability of expert testimony have evolved from Daubert's progeny, including "whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." Lauzon, 270 F.3d at 687.

***2** Although the Supreme Court in Daubert stated that the focus of the trial court's gatekeeping inquiry "must be solely on principles and methodology, not on the conclusions they generate," 509 U.S. at 595, the Court later acknowledged that "conclusions and methodology are not entirely distinct from one another." General Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Id. Thus, the district court may evaluate whether the studies or data upon which the expert relies are sufficient, either individually or in combination, to support the conclusions and opinions being advanced, there being "nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." Id.

The ultimate goal of the trial court's "gatekeeping" inquiry is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire, 526 U.S. at 152. To accomplish that "gatekeeper function," the trial court has discretion both in deciding how to evaluate the reliability of the expert testimony and whether the expert's relevant testimony is reliable. Id. In evaluating the admissibility of expert testimony, the Court must also be mindful that "[v]igorous cross-examination [and the] presentation of contrary evidence ... are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596. This last observation reflects the fundamental principle that Rule 702 is generally one of inclusion rather than exclusion.

B. BSC's Motion to Exclude Certain Testimony of Dr. Lagoudas

Medtronic identified Dr. Dimitris Lagoudas as a witness who will provide expert opinion testimony about whether stress-induced martensite forms in the RADIUSTM stent prior to the stent's deployment in the human body. Dr. Lagoudas analyzed whether stress-induced martensite forms in the RADIUSTM stent by using two separate methods. The first involved measuring the outside diameter of the deployment sheath of a RADIUSTM stent system at different temperatures. The second utilized a computerized Fininte Element Analysis to model a hypothetical stent system's behavior. [FN2] BSC moves to exclude any expert testimony regarding the measurements taken of the deployment sheath and any conclusions drawn from that data. [FN3]

> FN2. A "fininte element analysis" is a computer-based analysis method that calculates the response of a model by solving a set of simultaneous equations that represent the behavior of the structure under external loading. Structural Research & Analysis Corp., Glossary of Analysis Terminology, <http://www.cosmosm.com/support/

glossary.htm>

FN3. BSC does not seek to exclude the testimony of Dr. Lagoudas relating to his Finite Element Analysis ("FEA"). At the hearing on these motions, counsel for BSC stated that, while they believe Dr. Lagoudas' FEA is subject to significant criticism, they chose not to bring a Daubert motion to exclude it. (Hrg. Tr. at 27.) As BSC chose not to move to exclude Dr. Lagoudas' FEA according to the Court's scheduling order, the Court will not entertain such a motion before or during trial.

1. Background

Dr. Lagoudas is a professor of aerospace engineering and the Associate Vice President for Research at Texas A & M University. He is also the director of the Center for Mechanics of Composites and the director of the Active Materials and Intelligent Systems Laboratory, both of which are located at Texas A & M. For this case, Dr. Lagoudas contracted with Texas A & M University for the use of its Active Materials Laboratory and its equipment.

***3** Appendix 1 of Dr. Lagoudas' expert report describes, inter alia, the observations and measurements made with respect to two RADIUSTM coronary stents and their delivery systems: a 20mm RADIUSTM 3.5 system and a 31mm RADIUS TM 3.0 system. [FN4] The experiments conducted on each stent system are described below.

FN4. The designations "20mm" and "31mm" refer to the overall length of the stent. (See Lagoudas Expert Report, App. 1 § 1.2.3, Table 2.) Dr. Lagoudas indicated that the 20mm stent is designed for a maximum deployed stent diameter of 4.25mm whereas the 31mm stent is designed for a maximum deployed stent diameter of 3.75mm. (Lagoudas Expert Report, App. 1 § 1.3.1 at 7.)

a. Experiments with the 20mm stent

With respect to the 20mm RADIUSTM stent system, Dr. Lagoudas first caused the diameter of the sheath, which was constraining the stent, to be measured at various temperatures, starting with room temperature (22 C or 71.6 F). The stent and delivery system were cooled to -16 C (3.2 F) and additional diameter measurements taken. [FN5] The sheath and stent inside were then heated to body temperature (37 C or 98.6 F) and diameter measurements again taken. [FN6] The sheath and stent were further heated to 50 C (122 F), a temperature Dr. Lagoudas identified as the temperature used for the sterilization procedure during the manufacture of the stent. At 50 C, the diameter of the sheath was again measured. Finally, the stent and sheath were heated to 54 C (129.2 F), the maximum temperature allowable for the stent and delivery system as indicated on the packaging for the product, and diameter measurements were taken. At least five measurements of the sheath diameter were taken at each temperature point.

FN5. To cool the stent and delivery system to -16 C, the stent was brought to thermal equilibrium with the air inside a conventional freezer, the temperature of which was monitored with a thermocouple. (Lagoudas Expert Report, App. 1 § 1.2.1 at 3.)

FN6. For all measurements involving temperatures above room temperature, Dr. Lagoudas used a hot water bath consisting of approximately one liter of water. The sheath with the stent was immersed and left "for several minutes to ensure thermal equilibrium with the bath." (Lagoudas Expert Report, App. 1 § 1.2.1 at 3.)

The 20mm stent was then deployed from the polyethylene constraining sheath and an observational analysis of the sheath was performed. [FN7] The post-deployment sheath was measured five times at each of four temperature points at which diameter measurements had been taken prior to deployment: -16 C, 22 C, 37 C, and 50 C. [FN8] Dr. Lagoudas compared the diameter of the sheath pre-deployment (i.e., with the stent inside) to the diameter of the sheath post-deployment (i.e., without a stent inside) and calculated the value of the pressure exerted on the sheath by the stent at room temperature and human body temperature. [FN9] From those calculations, Dr. Lagoudas observed as follows:

FN7. "After removal of the stent from the sheath, the sheath is no longer of uniform diameter: it varies in a wavy pattern along the sheath." (Lagoudas Aff. ¶ 38.)

FN8. Dr. Lagoudas indicates that these measurements were taken at two different times. (Lagoudas Aff. ¶ 38.) Initially, after deployment of the stent, the sheath diameter was measured at room temperature and body temperature. The delivery system was then "temporarily stored" in the manufacturer's shipping box and later removed from the shipping box so that two more measurements could be taken--this time at -16 C and 50 C. The post-deployment diameter measurements were taken at one physical location on the sheath for the first round of measurements (i.e., the 22 C and 37 C temperature points) and at another physical location on the sheath for the second round of measurements (i.e., the -16 C and 50 C temperature points.) There was no effort to ensure that, as between the first and second rounds of post-deployment measurements, the measurements were made at the same physical location on the sheath. (Id.)

FN9. To estimate the average radial stress imparted on the sheath by the presence of the stent, Dr. Lagoudas used a formula which he identified as being for "a thin walled cylinder." Two of the variables called for by the formula were the elastic modulus of polyethylene (for which Dr. Lagoudas stated he used "the standard value" of 0.4GPa) and the sheath wall thickness (which Dr. Lagoudas stated was measured to be 0.0635mm). (Lagoudas Expert Rep.App. 1 § 1.2.7 at 5.)

The increase in the diameter of the sheath, measured by comparing its diameter before deployment with its diameter after deployment, at equal temperatures, indicates the presence of stresses in the sheath. After deployment, the sheath is not in contact with any external body, and therefore it should be in a zero stress state. Before deployment, however, the internal surface of the sheath is in contact with the stent, which causes the sheath to radially expand. Any thermal expansion effects are taken into consideration by measuring the difference in the sheath diameter before and after deployment at equal temperatures. (Lagoudas Expert Report, App. 1 § 1.2.7 at 5.) Dr. Lagoudas also indicated that "[s]ome relaxation of the stresses may occur due to softening of the polyethylene material at higher temperatures." (Id. at 6.)

b. Experiments with the 31mm stent

*4 Dr. Lagoudas states that the same techniques used to measure the diameter of the 20mm stent system were employed to measure the diameter of the 31mm stent system. (Id. § 1.3.1 at 6.) The temperature changes to which the 31mm stent system was subjected were more complex than those the 20mm stent system underwent. The 31mm stent system was subjected to two full cycles of temperature changes that started from room temperature (22 C), rose to body temperature (37 C), rose further to sterilization temperature (50 C), cooled to body temperature, cooled further to room temperature, dropped to -16 C, and returned to room temperature. Thus, the experiments with the 31mm stent system generated seventeen temperature points at which measurements of the diameter of the stent sheath was made.

The 31mm stent was not deployed; therefore, Dr. Lagoudas did not cause the diameter of the sheath to be measured at various temperatures when empty. Instead, Dr. Lagoudas used the smallest diameter measurement for the pre-deployment sheath (occurring at -16 C) as a baseline for comparing diameters and for calculating "the additional radial stresses as the stent is heated above -16 C." (Lagoudas Expert Report, App. 1, § 1.3.1 at 7.)

2. Analysis

BSC moves to exclude any testimony by Dr. Lagoudas about his measurements of the RADIUSTM stent systems or about any opinions or inferences he drew therefrom. BSC contends that such testimony is unreliable under Daubert and its progeny because the methodology Dr. Lagoudas employed to obtain and analyze the data in question is unreliable. Medtronic responds that one expert's criticism of another expert is an inappropriate basis for striking expert testimony. Medtronic contends that resolving conflicts between the testimony of each party's expert is an inquiry that goes to the weight to be afforded Dr. Lagoudas' testimony, not its admissibility. [FN10] Medtronic asserts that Daubert and its progeny stand for the proposition that the scientific method requires testing; because Dr. Lagoudas performed laboratory tests on the RADIUS TM stent system using equipment typically used by himself and others for testing at Texas A & M, his proposed testimony meets the threshold reliability requirements of Daubert and Rule 702.

FN10. Dr. Lagoudas devotes several paragraphs in his responsive affidavit comparing, in very general terms, the "methodology" he used to investigate the RADIUSTM stent system to the methodology he used in an accident investigation conducted for NASA. (Lagoudas Aff. ¶¶ 18-20.) Dr. Lagoudas states that he began each investigation with a "briefing" on the problem to be addressed. He indicates that the next step in each investigation was to ask for and receive information about the object under investigation, to obtain alloy specimens for that object, and to obtain and review data related to the problem to be addressed. Dr. Lagoudas then disclosed that, for each investigation, he formulated a plan as to how to examine the problem to be addressed, both using a finite element analysis to model the system and performing experiments. Dr. Lagoudas asserts that for both the NASA investigation and this case, he "made no compromises and cut no corners." (Lagoudas Aff. ¶ 20.) The Court finds this generalized "comparison" to be non responsive to the specific criticisms leveled by BSC.

Engineering is a discipline that rests upon scientific knowledge, and "[e]ngineering testimony rests upon scientific foundations." Kumho Tire, 526 U.S. at 148, 150. Among the factors relevant to assessing the reliability of scientific-based testimony, the Supreme Court has stated that "in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error ... and the existence and maintenance of standards controlling the technique's operation." Daubert, 509 U.S. at 594.

Medtronic is correct that some of BSC's criticisms of Dr. Lagoudas' methodology, such as his treatment of "conflicting data," go to the weight of his proposed testimony rather than its admissibility. Those issues are more properly fodder for cross-examination. See United States v. Pico, Inc., 266 F.3d 864, 871 (8th Cir.2001) (ruling that, unless expert testimony is "so fundamentally unsupported" that it cannot be of any assistance to the jury, the sufficiency of the factual basis for such testimony goes to weight and credibility, to be explored on cross-examination, not admissibility), cert. denied, 535 U.S. 1095, 122 S.Ct. 2291, 152 L.Ed.2d 1050 (2002). [FN11]

FN11. For example, BSC argues that Dr. Lagoudas made use of an inappropriate instrument when taking measurements of the stent systems. Relying on texts regarding the science of physical measurements, BSC contends that the caliper micrometer Dr. Lagoudas used is designed to measure rigid objects for which one can determine whether the calipers have made contact with the object by touch. According to BSC, Dr. Lagoudas' assistant could not have determined whether the calipers made contact with the sheath by touch because the sheath (and the stent inside) are not rigid, but rather are compressible. The assistant would have to determine whether the calipers made contact with the sheath by sight, introducing an element of error into the measurements. Dr. Lagoudas responds that he made use of the same instruments that he and others routinely use for research in the Materials and Structures Laboratory at Texas A & M. He describes the micrometer used as "a standard, caliper-type mechanical micrometer, a micrometer that uses a vernier scale, i.e., a vernier caliper." (Lagoudas Aff. ¶ 21.) Furthermore, he indicates that the risk of the micrometer deforming the sheath was low because the ' portion of the micrometer touching the sheath was very small; the "jaws" of the caliper were tapered to a wedge-shaped as opposed to being anvil-shaped. (Lagoudas Aff. ¶ 52.)

***5** Similarly, the Court finds little merit in BSC's complaint that Dr. Lagoudas' methodology has not been the subject of peer review or received general acceptance in the relevant community. BSC has not made a threshold showing that the question of whether stress-induced martensite forms in nitinol medical devices that experience wide fluctuations in temperature is one about which other engineers are interested or have written. The particular issue Dr. Lagoudas addressed in his analysis appears to be narrow and specific to this case. Therefore, it is not particularly surprising that Dr. Lagoudas' methodology has not been peer reviewed or discussed. See Kumho Tire, 526 U.S. at 151.

Another criticism of Dr. Lagoudas' method, however, is more problematic. BSC contends that Dr. Lagoudas' methodology violates scientific practice and, hence, is unreliable because he fails to exclude an equally plausible explanation for the phenomenon he observed--changes in the rate of change for the diameter of the 31mm stent system. BSC asserts that such changes in the rate of change

(evidenced by a "kink" in Dr. Lagoudas' graph of the sheath's diameter as a function of temperature) could certainly be attributable to the deployment sheath itself rather than the nitinol stent inside the sheath. BSC argues that, because Dr. Lagoudas failed to employ a control (i.e., an empty sheath), he failed to employ proper standards for his experiments.

Dr. Lagoudas responds that he accounted for the thermal expansion effects of the deployment sheath in his Initial Expert Report and the effect of temperature changes on the deployment sheath itself. Dr. Lagoudas stated in his Initial Expert Report that "[a]ny thermal expansion effects are taken into consideration by measuring the difference in the sheath diameter before and after deployment at equal temperatures." (Lagoudas Expert Report, App. 1 § 1.2.7 at 5 (emphasis added).) Dr. Lagoudas contends that he thus established a "control" that accounted for the effect of temperature changes on the sheath and eliminated the obvious possibility that the changes observed in the diameter of the sheath were attributable to the sheath itself.

Dr. Lagoudas measured the difference in the sheath diameters before and after deployment at equal temperatures, however, only with respect to the 20mm stent system He did not use such a methodology for the 31mm stent, although that is the stent from which he has derived the data that reportedly support his theory that stress-induced martensite formed in the stent as the stent system cooled. [FN12] Thus, Dr. Lagoudas did not maintain a consistent procedure in evaluating the two specimen stent systems. Because the effect of thermal expansion on the sheath is taken into account "by measuring the difference in the sheath diameter before and after deployment at equal temperatures," and because Dr. Lagoudas did not make take such measurements for the 31mm stent system, the Court can only conclude that Dr. Lagoudas did not take that thermal expansion effect into account for the very stent system from which he has derived the data on which he purports to base his opinion.

FN12. The 20mm stent system was not subjected to two complete cooling cycles, as the 31mm stent system was.

***6** The Court further notes that, when evaluating the 31mm stent system and calculating the average radial stress (pressure) imparted on the sheath by the stent, Dr. Lagoudas departed from the technique he used for the 20mm stent system. [FN13] Instead of comparing the diameter of the sheath when unstressed (i.e., empty) to the diameter of the sheath when under stress (i.e., with the stent inside) at the same temperature, Dr. Lagoudas started with the smallest diameter of the stent under stress (which occurred at -16 C) and, using that stress figure as a baseline, calculated what he described as the "additional radial stresses as the stent is heated above -160C." Consistency in technique is an important part of a scientist's or engineer's methodology. Daubert, 509 U.S. at 594 (directing a trial court to "consider the known or potential rate of error ... and the existence and maintenance of standards controlling the technique's operation."). Based on the foregoing, the Court cannot conclude that Dr. Lagoudas has exercised the same degree of care and intellectual rigor in the RADIUSTM stent experiments as would be exercised in his regular professional work.

FN13. That radial stress applied by the stent to the sheath, Dr. Lagoudas asserts, is the same in magnitude as the radial stress applied by the sheath to the stent. (Lagoudas Expert Report, App. 1 § 1.2.7 at 6.)

Having reviewed the Initial Expert Report and Dr. Lagoudas' affidavit opposing the Daubert motion, the Court cannot find it to be an insignificant omission that Dr. Lagoudas failed to measure an empty 31mm deployment sheath at the same temperature points for which the sheath with stent was measured. That omission represents a departure from the technique employed to evaluate the 20mm stent system and a failure, by the terms of his own expert report, to account for the thermal expansion effects of the sheath used for the 31mm stent system. [FN14] Medtronic has not established by the greater weight of the evidence that Dr. Lagoudas considered and excluded an alternative explanation for the phenomenon he observed with respect to the 31mm stent system. Accordingly, Dr. Lagoudas is precluded under Federal Rule of Evidence 702 from testifying about the measurements taken of the specimen RADIUSTM stent systems and any inferences or opinions derived therefrom.

FN14. The Court also notes that, although Dr.

> Lagoudas recognized that "[s]ome relaxation of the stresses may occur due to softening of the polyethylene material at higher temperatures" (Lagoudas Expert Report, App. 1, § 1.2.7 at 6), he did not address the extent of the "softening" that would occur as the temperature of the polyethylene sheath increased.

C. BSC's Motion to Exclude Certain Testimony of Goldscheider

Medtronic has identified Robert Goldscheider as a witness who will opine as to the appropriate amount of damages Medtronic should receive assuming that infringement is established and the patents-in-suit are found to be valid. Goldscheider disclosed several opinions in an Initial Expert Report, dated December 11, 2000. At that time, however, he stated that he was "not yet in a position to produce an opinion in monetary terms on damages in the form of a reasonable royalty." (June 7, 2002 Jackson Aff., Ex. A at ¶ 21.) Goldscheider provided a supplemental expert opinion on January 26, 2001, in which he indicated that a reasonable royalty in this matter would be 19.8%. (Id., Ex. H.) BSC moves to preclude Goldscheider from testifying at trial on topics about which he was unprepared to testify at his expert deposition. [FN15]

> FN15. BSC does not seek to exclude all of Goldscheider's testimony, only his testimony on those issues about which he was unable to testify at his deposition.

1. Background

*7 Robert Goldscheider is presently the chairman of the International Licensing Network, Ltd., a firm of technology management consultants. (Goldscheider Expert Report ¶ 1.) Goldscheider is an attorney, who was admitted to practice in New York State in 1956. (Id. ¶ 2.) For over forty-two years, Goldscheider's professional activities have focused on the many aspects of the licensing process, both commercial and legal. (Id.) Medtronic retained Goldscheider to provide an expert opinion on damages within the context of 35 U.S.C. § 284. (Id. ¶ 1.) Goldscheider determined that a hypothetical negotiation for a licensing agreement would be the appropriate methodology for placing a value on infringement damages in this case. (Id. ¶ 6.)

Two of the several issues Goldscheider considered before rendering his damages opinion are the subject of this motion in limine. BSC asserts that Goldscheider should be precluded from testifying about "convoyed sales" (that is, sales of non-patented products that are generated by the sale of the patented product) and about the value of the two patents-in-suit relative to the entire "bundle" of intellectual property rights Medtronic acquired from Raychem through a 1996 Patent Assignment Agreement. Goldscheider's discussion, in both his expert reports and his deposition, of each issue is set forth below.

a. Value of the Patents-in-suit Relative to the Raychem Bundle

Goldscheider states that, in preparing his initial expert opinion, he relied on or took into account certain facts and circumstances. (Id. ¶ 8.) Among these was the fact that

> The said Jervis Patents ... were acquired by Medtronic from Raychem Corp. on August 28, 1996, pursuant to a patent assignment agreement that conveyed a portfolio of intellectual property consisting of the said Jervis patents, as well as several additional patents, patent applications and invention disclosures. The total consideration paid by Medtronic for this bundle of rights was $25 million. It is considered relevant to evaluate the relative value of the said Jervis patents (which are understood to be the "flagship" rights in the bundle in relation to the remainder). [FN16]

> FN16. In his Initial Expert Report, Goldscheider refers to the two patents-in-suit as "the said Jervis patents." (Goldscheider Expert Report, ¶ 8(a).) (Id. ¶ 8(b) (emphasis added).) At deposition, BSC's counsel asked whether, in the course of preparing his report, Goldscheider had evaluated or considered the non-Jervis components of the patent portfolio. He replied:
>
> A: I tried to. I requested of counsel and Mr. Gallagher to see if they have seen anything in the enormous documentation in the case which focuses on that point, and I haven't seen anything.
>
> The more I look at it, though, it seems to me that the two Jervis patents are the overwhelming percentage of the value here. It's the only thing that people really talk about, and I get the impression that virtually all of the value is attributed to those two patents and that the value of the whole portfolio

would not change if one were simply talking about those two patents.

***8** That's as much a gut feeling as anything else, but I just haven't seen anything which differentiates from that. Everybody seems to talk about the Jervis patents and that's it, even though it was realized that it was bought in a bundle.

Q: So you are saying for purposes of your report that you are attributing all or substantially all of the value of the 25 million dollars to the Jervis patents?

A: Yes.

Q: Do you know why Medtronic paid 25 million dollars for the patents?

A: I have not had an opportunity to speak to any Medtronic executives about that, but I speculated about it.

(Goldscheider Dep. at 154-55 (emphasis added).) Goldscheider's "speculation" was based on an impression that the patents-in-suit are "considered to be broad and cover a lot of applications." (Id. at 155.) BSC's counsel asked for the basis of Goldscheider's statement that the patents are broad. Goldscheider replied:

A: I have the impression from what I've seen and what I've read that these patents have not been attacked for being invalid, and I get the impression that they cover a variety of products in addition to stents, that they deal with this Martin Sythe phenomenon, which can have many applications and the Jervis patents would cover all of them.

* * * *

Q: You said you read some things. What did you read that supports your statement, your understanding, that these are broad patents?

A: I'm not sure now whether it was the Latham deposition. It could have been Mr. Friedman's interpretation of what Kenyon & Kenyon said. I understand that Fish & Richardson, which is a firm I know and of whom I have a very serious respect, has also reviewed the patents. I have indicated that I'm going to ask more about that, but it apparently is something that was considered to be very valuable. Boston Scientific thought likewise, which reinforces it. I suspect that Medtronic knew that Boston Scientific was interested in these patents and didn't want Boston Scientific to have them, but I cannot at this sitting give you any firsthand report from a Medtronic official why they were prepared to pay 25 million for this, but I intend to ask that question when I get an opportunity to do so.

(Id. at 156-57 (emphasis added).) [FN17]

FN17. This testimony does not substantiate Medtronic's assertion that Goldscheider relied on the report of BSC's damages expert, Mr. Friedman, in forming an opinion that the patents-in-suit are valuable because they are broad. (See Medtronic's Opp'n to Defs.' Mot. in Limine to Exclude Test, of Goldscheider at 5.)

Goldscheider also stated in his initial report that he considered the fact that the bundle of intellectual property rights Medtronic acquired in 1996 encompassed two pre-existing license agreements. Goldscheider observed that

> [n]either license relates to coronary stents, nor has either license resulted in any royalty payments to Medtronic subsequent to the assignment. Therefore, they do not serve to "dilute" the significance of the $25 million payment made by Medtronic to Raychem Corp., of which the said Jervis patents are considered to be the prime source of value.

(Id. ¶ 8(i) (emphasis added).) Goldscheider also notes that

> Boston Scientific ... appreciated the considerable value of the Jervis patents. In a 30(b)(6) deposition, taken on December 1, 2000, of Francis P. Grillo, a Boston Scientific vice president selected to testify on behalf of his company. Mr. Grillo acknowledged that the primary value of the portfolio of patents acquired by Medtronic on August 28, 1996 was the said Jervis patents .

***9** (Id. ¶ 8(q) (emphasis added).) [FN18] Finally, in opining about a hypothetical negotiation in mid-1998, Goldscheider identified fifteen issues that would have been considered by the parties, including the following:

FN18. Goldscheider cites testimony from Grillo stating that, about three weeks before Medtronic purchased the Raychem bundle, Boston Scientific had offered Raychem, in writing, $15 million for the portfolio and that Boston Scientific later orally offered to purchase Raychem's portfolio for around $30 million. (Goldscheider Expert Report ¶ 8(q).) Goldscheider also cites Grillo's testimony that the $30 million figure was "arrived at by Boston Scientific following consultation with, and on the basis of advice from, investment bankers, as well as the prominent patent law firm of Kenyon and Kenyon, who performed an evaluation of the portfolio as to patent validity." (Id.) Observing that

> total sales of RADIUSTM stent systems between July 1998 and September 2002 were about $74 million (id. ¶ 15(b)), Goldscheider asserts that the $15 million offer ... calculates as an equivalent to a royalty of 20 per cent, which turned out to be too low and was rejected by Raychem. It should also be noted that the actual offer of $30 million ... made by Boston Scientific applied to actual total sales to date amounts to more than 40 per cent of the actual total sales following introduction of the RADIUSTM Stent System. The higher figure, which was obviously in the mind of Boston Scientific, is thus highly relevant in the context of a hypothetical negotiation. (Id. (emphasis in original).) Paragraph 15(b) of Goldscheider's Expert Report does not support Medtronic's assertion that Boston Scientific offered to purchase the Raychem portfolio "based largely on the perceived value of the Jervis patents." (Medtronic's Opp'n to Defs.' Mot. in Limine to Exclude Test, of Goldscheider at 3-4.)

Boston Scientific eventually offered "about $30 million" for the patent portfolio, after performing due diligence which included an investigation as to the validity of the patents and an investigation as to whether the RADIUSTM stent project fell within one or more claims of one or more patents of the Jervis portfolio. Deposition of Frank Grillo at 94 & 102.

It appears that Boston Scientific also regarded the said Jervis patents to be the "flagship" properties in the bundle. Deposition of Frank Grillo at 80-81 & Bates No. BSC055669.

(Id. ¶¶ 19(g) & (h) (emphasis added).)

b. Convoyed Sales

Goldscheider's analysis of what constitutes a "reasonable royalty" rate for infringing products includes the consideration of "convoyed sales." Goldscheider opines that the issue of "convoyed sales" favors Medtronic and points to a relatively high royalty rate. (Goldscheider Expert Report ¶ 16(d).) In discussing "convoyed sales," Goldscheider first states that the RADIUSTM stent "is always sold together with its placement catheter, qualifying such combined product for the entire market value rule." (Id. ¶ 10.) Goldscheider then asserts that "such combined product requires the use of balloons, guide wires, and guide catheters for the positioning of the stent, and sales of such products should be considered as being convoyed." (Id. ¶ 11.) Goldscheider also cites an April 1996 internal SCIMED document entitled "Concept/Development [Products Economy Request]," which he summarizes as indicating that "one of the expected results of the introduction of a shape memory stent is that it '[p]rovides bundling opportunities with SCIMED's full line.' " [FN19] (Id. ¶ 12 (quoting Bates No. BSC025245).) Goldscheider states that this passage says to him "that the impact of convoyed sales in this case is probably significant. Even if we are eventually unable to quantify exactly the dimension and profitability of such convoyed sales, this reality nevertheless exerts an upward pressure on what constitutes a reasonable royalty here." (Id.)

> FN19. Paragraph 12 of Goldscheider's Expert Report does not support Medtronic's assertion that Goldscheider "relies explicitly on internal SciMed documents that speak to the opportunities for such convoyed products and that mention the significant benefit that SciMed might enjoy from those products." (Medtronic's Opp'n to Defs.' Mot. in Limine to Exclude Test, of Goldscheider at 2.) Goldscheider does not rely on documents, but rather on a single document from 1996. Furthermore, the passage Goldscheider quotes from refers to "bundling opportunities," not convoyed products. Goldscheider testified that "convoyed products" are those products that are sold together with the allegedly infringing product either to help make the allegedly infringing product work or otherwise to be used together with the allegedly infringing product; separate product lines do not become "convoyed products" simply because they are sold at the same time as the allegedly infringing product. (Goldscheider Dep. at 89 (discussing example in which a copier is the alleged infringing device and the customer buys both a copier and a camera).) The SciMed document refers to opportunities to bundle the stent with the company's "full line," which would encompass product lines separate from coronary stents.

After reviewing additional documents produced by BSC to Medtronic, Goldscheider determined that

> certain additional products are often sold and used in conjunction with the RADIUSTM stent system. These products include inflation devices, IVUS catheters, rotablator burrs, rotablator advancers, and rotablator wires.

(Goldscheider Supplemental Expert Opinion ¶ 4.) Goldscheider indicates that the "extent of the sales of such convoyed products would have a direct effect on the damage figure that I consider appropriate if the Jervis patents are found to be valid and infringed." (Id.) He therefore supplemented his comments regarding the "convoyed products" factor for the reasonable royalty calculation as follows:

> ***10** ... the additional products noted in Paragraph 4 of this Supplemental Opinion might also be considered as being directly infringing under the doctrine of the entire market value rule. I have not, however, yet had an opportunity to discuss this issue in sufficient detail with Medtronic's executives or its attorneys, but hope to do so as promptly as reasonably possible. If this investigation should indicated that these added items should merely be considered convoyed sales, the theory of this opinion would not change, but the amount of such convoyed sales would increase.

(Id. ¶ 5(a).) At his deposition, Goldscheider was asked whether he had read certain paragraphs of a report by BSC's damages expert, Alan Friedman, pertaining to "convoyed sales." Goldscheider testified:

> ... every time you sell a RADIUSTM stent, you have a chance to sell some additional products other than the placement catheter, which is part of the entire product, but there are other products that you will sell. Whether it be a RADIUSTM or a NIR, they both have conveyed sales with them. I don't know whether one has more than the other, but there are convoyed sales in both cases, and I believe that is relevant.
>
> Whatever they are, perhaps Mr. Gallagher and his colleagues working with your accounting people will be able to isolate and identify what they are and also determine what the profitability of those convoyed sales are, and then one can work out a royalty on that. I at this moment don't know exactly what the convoyed sale products are or indeed what their profitability is, but once that information is worked out by Mr. Gallagher with your people, then there is no problem.

(Goldscheider Dep. at 87 (emphasis added).)

BSC's counsel later asked Goldscheider about a list of products that appears in Mr. Friedman's expert report: "ultrasound catheters, atherectomy products, inflation devices, IVUS catheters, rotablator burrs, rotablator advancers, and rotablator wires." (Goldscheider Dep. at 90-91.) Goldscheider confirmed that those products "seemed to us to be what are the type of thing that would be sold together with a basic stent." (Id. at 91.) The following exchange then took place:

> Q: Do you know for certain whether those are convoyed products as you define that term?
>
> A: I do not, and I'm not the person to make that decision.
>
> Q: Okay. Do you know what a rotablator is?
>
> A: I've heard it described to me, but I really don't know at this time, but you bring up an interesting point, because when I testify, I will.
>
> It is my practice to visit the factory of clients on behalf of whom I'm testifying so that I can literally pick up, see, smell, taste if necessary, whatever the licensed products are. So I've already requested the Robins Kaplan firm to arrange for me, hopefully in the company of Mr. Gallagher, to visit their plant, which I'm told is in northern California, to see these products. Indeed, I've never at this moment been able to compare, a NIR balloon stent from a Palmaz-Schaz.
>
> ***11** So, therefore, I'm going to know that, because I think it is important. And if you ask me at trial what convoyed products look like, I will know. I simply haven't had a chance to do it during my assignment up to now.
>
> * * * * *
>
> Q: But as we sit here today, you can't tell me that the items that we looked at and I read into the record at the top of page 15 of Mr. Friedman's report are, in fact, convoyed products; is that correct?
>
> A: I believe they are, and I think there's a reference to them in my supplemental report. We've seen evidence that these things go along with the stents and, therefore, it was my interpretation that they would be part of the convoy, that they would be convoyed.
>
> Q: Would you explain to me your understanding of how a rotablator burr is a convoyed product with a RADIUSTM stent?
>
> A: I can't tell you as I sit here, but I promise to tell you at trial. The point is it may be something to help you to affix the stent, to clean the stent, to do something with the stent that you would want one of those if you were going to be using a stent. Exactly how it works, as I told you, I'm not yet up to speed on that, but I will be.

(Id. at 91-92, 94-95 (emphasis added).)

2. Analysis

BSC contends that Goldscheider has not satisfied the expert disclosure requirements of Rule 26(a)(2) and to allow him to testify about "convoyed products" or about the value of the patents-in-suit vis-a-vis the entire "Raychem bundle" would constitute "trial by ambush." BSC further argues that Rules 702 and 703 of the Federal Rules of Evidence do not permit an expert to testify about conclusions that lack factual support; accordingly, to the extent Goldscheider could not explain at his deposition the facts underlying his conclusions and opinions, he should be precluded from testifying to those conclusions or opinions at trial.

Rule 702 of the Federal Rules of Evidence provides that a witness may offer expert opinion testimony if, among other things, "the testimony is based upon sufficient facts or data." Fed.R.Evid. 702. "Proposed testimony must be supported by appropriate validation--i.e., 'good grounds,' based on what is known." Daubert, 509 U.S. at 588. The Federal Rules of Civil Procedure require each witness who will testify at trial as an expert to prepare and sign a written report containing, inter alia, "a complete statement of all opinions to be expressed and the basis and reasons therefor [and] the data or other information considered by the witness in forming the opinions." Fed.R.Civ.P. 26(a)(2). Where a witness has not solidified his expert opinions (and the basis and reasons therefor), opposing counsel are unable to explore the soundness of the proposed testimony. See Elswick v. Nichols, 144 F.Supp.2d 758, 762-63 (E.D.Ky.2001).

As of his deposition, Goldscheider could not identify what products (if any) are sold in "convoyed sales" or what the volume of "convoyed sales" was. He had already opined, however, that the level of "convoyed sales" associated with the RADIUSTM stent indicates that a relatively high royalty rate is appropriate. Similarly, Goldscheider testified that he believed the patents-in-suit accounted for virtually all of the $25 million Medtronic paid for the Raychem portfolio; that belief was, in his own words, however, "as much a gut feeling as anything else." Although the intellectual property rights Medtronic purchased from Raychem were ascertainable, Goldscheider had not, as of his deposition, tried to determine the value to Medtronic of any of the items in that portfolio other than the patents-in-suit.

***12** Furthermore, the only evidence corroborating Goldscheider's "gut feeling" was (1) vague and conclusory testimony from the 30(b)(6) deposition of Boston Scientific and (2) an August 8, 1996 internal Boston Scientific document stating that "the primary value of the patents are the Jervis patents which are broad, including method and device claims." (New Bus. Dev. Exec. Summ. at BSC 055669 (attached to June 21, 2002 Grant Aff. as Ex. C).) The Boston Scientific Executive Summary, however, discussed three Jervis patents issued in the United States (of which only one is a patent-in-suit), two pending U.S. applications (of which one became a patent-in-suit), and a "[b]asic Jervis patent issued in Europe in 1995" that was effective in nine European countries and Canada and was pending in Japan. The conceptual gulf between "primary value," as discussed in the Boston Scientific document, and "virtually all of the value," which Goldscheider would attach to the two patents in suit, is both nebulous and potentially sizable.

The Court concludes that, with respect to the opinions and inferences pertaining to "convoyed sales" and the value of the patents-in-suit vis-a-vis the total Rayehem portfolio, "there is simply too great an analytical gap between the data and the opinion proffered." Joiner, 522 U.S. at 146. Although Goldscheider has opined that (a) virtually all of the $25 million Medtronic paid for the Rayehem portfolio was attributable to the patents-in-suit and (b) the "convoyed sales" associated with the RADIUSTM stent warrants a relatively high royalty rate, he could not identify a reliable factual basis for those opinions. In short, Goldscheider put the cart before the horse. Medtronic has not established that Goldscheider's proposed expert testimony on the above-described issues is either sufficiently reliable or relevant to be admissible. [FN20] Accordingly, Goldscheider is precluded from testifying on those issues or referring to those issues to support any opinion at trial concerning an applicable "reasonable royalty rate" or hypothetical license negotiations. [FN21]

> FN20. Having concluded that Goldscheider's testimony on those two issues does not meet the admissibility standards of the evidence rules on expert testimony, it is unnecessary to consider

whether the testimony should be excluded on the grounds that Medtronic did not comply with the expert disclosure requirements of Rules 16 and 26.

FN21. The impact, if any, that the exclusion of testimony on these two issues will have on Goldscheider's opinions regarding damages is not before the Court.

D. Medtronic's Motion to Exclude Testimony of Drs. Bhattacharya and Muskivitch

Medtronic has challenged the admissibility of expert testimony that BSC intends to introduce pertaining to (a) whether the RADIUSTM stent infringes the patents-in-suit and (b) whether the patents-in-suit were anticipated in an article written by Dr. Cragg about nitinol vena cava filters. Dr. Kaushik Bhattacharya will opine that no stress-induced martensite forms in the RADIUS TM stent system. He will also opine, with respect to BSC's anticipation defense, that stress-induced martensite did form in the two nitinol vena cava filters that Dr. Cragg had drawn back into their catheters for redeployment. Dr. Muskivitch will also opine that stress-induced martensite formed in the vena cava filters described in the Cragg II paper as having been "redeployed." Dr. Muskivitch's opinions are based on a Finite Element Analysis ("FEA") that he performed.

***13** Medtronic argues that Dr. Bhattacharya's opinion regarding the presence of stress-induced martensite in the RADIUSTM stent system must be excluded because the methodology Dr. Bhattacharya used to arrive at that opinion is unsound. Specifically, Medtronic complains that Dr. Bhattacharya never performed any tests on an actual RADIUSTM stent product and never considered whether stress-induced martensite might form after manufacture, thus missing a whole part of the product's life cycle.

With respect to the vena cava filters from the Cragg II paper, Medtronic contends that Dr. Bhattacharya's proposed opinions about whether stress-induced martensite formed must be excluded because he never tried to replicate the procedure described in the Cragg II paper and because he improperly assumed that, when the publication says the filters were "successfully repositioned," those words meant the filters had regained their original shape. Medtronic seeks to exclude Dr. Muskivitch's opinions on the formation of stress-induced martensite in the filters on the grounds that (1) an FEA, by itself, is not a generally accepted, reliable methodology, and (2) Dr. Muskivitch made numerous unfounded assumptions concerning the nitinol vena cava filters, thereby rendering his FEA unreliable.

1. Background

a. Dr. Bhattacharya

Dr. Bhattacharya has been on the faculty of the California Institute of Technology since 1993 and is presently a Professor of Applied Mechanics and Mechanical Engineering there. (Bhattacharya Expert Report ¶ 2.)

i. Non-infringement

In his Rebuttal Expert Report, Dr. Bhattacharya devotes two pages to the question of whether the RADIUSTM stent, at any time, displays stress-induced martensite. (Bhattacharya Rebuttal Expert Report at 17-18.) The heart of Dr. Bhattacharya's opinion is his theory of what happens to the RADIUSTM stent system when the temperature of the stent rises above the alloy's A S temperature (10 C or 50 F):

> As the temperature goes above A S , the constrained, thermally induced martensite attempts to transform to austenite. The sheath prevents it from doing so by constraining the thermally induced martensite. This causes an internally generated, temperature dependent stress to be generated. This internally generated, temperature dependent stress is referred to as reversion stress (K. Madangopal, R. Ganesh, Krishnan and S. Bannerjee, Reversion Stress in Ni-Ti Shape Memory Alloys, Scripta Metallurgica 22, 1593-1598, 1988). It has been demonstrated in experiments (e.g., Madangopal, et al., above) that, at any given temperature, the value of reversion stress is below the value of stress necessary to form stress-induced martensite at that temperature. Thus, at any given temperature above A S , the stress in the stent restrained in the sheath will be below the value required to transform austenite to stress-induced martensite at that temperature.

***14** (Id.) Dr. Bhattacharya further opines that, as

the temperature of the stent system rises and falls, the reversion stress also rises and falls but never exceeds the amount necessary to form stress-induced martensite. (Id. at 18.) From the face of the Rebuttal Expert Report, the basis for Dr. Bhattacharya's opinion appears to be research on "reversion stress" performed by Madangopal, et al.

ii. Anticipation

To investigate whether stress-induced martensite formed in the nitinol vena cava filters that were "redeployed" during the experiments by Cragg, et al., Dr. Bhattacharya examined the Cragg II paper itself. (Bhattacharya Expert Report ¶ 7.) He compared Figures 1(A)-(C) of the paper, showing the mandrel used to make the nitinol vena cava filters and specimen filters after manufacture, with Figures 2(A)-(B), venograms of a filter that had been in place in an animal for about six weeks. (Id. ¶ 10.) From these figures, he concluded that "the deployed filter regained approximately all of its original shape. Thus, these figures also show that the transformation temperature of the nitinol wire is less than body temperature and that the deployed filter was in the austenite state." (Id.) Dr. Bhattacharya reasoned that, when a deployed filter was drawn back into the catheter, the filter would have become deformed. He stated that only three deformation mechanisms are possible in a nitinol wire that is above its transformation temperature (i.e., in its austenitic state): ordinary elasticity, ordinary plasticity, and stress-induced martensite. (Id. ¶ 13.)

Using what he described as "accepted methods, conservative assumptions, and the information in the [Cragg II] paper," Dr. Bhattacharya mathematically estimated the strain involved in drawing the filter back into the catheter. (Id. ¶¶ 17-20.) These calculations produced estimated strains in the range of between 2% and 4.4%. Dr. Bhattacharya stated that the ordinary elasticity of austenite can accommodate strains of at most 0.5% to 1%. (Id. ¶ 14.) Given the estimated strains in the filter when withdrawn back into the catheter, he ruled out ordinary elasticity as the cause of the deformation the Cragg II paper reported. (Id. ¶ 14.)

Dr. Bhattacharya also ruled out ordinary plasticity, which denotes a permanent change in the form of an object. The Cragg II paper did not report that, when he redeployed the filter after withdrawing it into the catheter, the filter stayed in its deformed configuation. Dr. Bhattacharya observed that, on the contrary, the Cragg II paper indicated that the filters were "successfully repositioned." (Id. ¶ 15.)

Dr. Bhattacharya concluded that stress-induced martensite was the mechanism that produced the deformation as the two filters were withdrawn back into their catheters. (Id. ¶ 16.) That is, stress-induced martensite was formed from austenite as the deployed filter was drawn back into the catheter. (Id. ¶ 12.) Thus, Dr. Bhattacharya made a finding, "based on the information provided in the paper, ... that the repositioning of the deployed filter by withdrawing it back into the catheter and then redeploying it ... was affected through stress-induced martensite." [FN22] (Bhattacharya Expert Report ¶ 11.)

> FN22. To support that finding, Dr. Bhattacharya cites the following three passages from the Cragg II paper: If the position of the filter was not optimal, it could be withdrawn into the catheter and positioned again. In two animals, the original placement of the filters was not optimal. These filters were withdrawn into the catheter and successfully repositioned The nitinol spiral filter developed in our laboratory possesses several advantages over other vena cava filters: ... (3) it can be withdrawn and repositioned easily.... (Bhattacharya Expert Report ¶ 11; Cragg II Paper (attached as Ex. H to the June 7, 2002 Aff. of Celeste Grant).)

b. Dr. Muskivitch

***15** John Muskivitch has a doctorate in Civil Engineering from Drexel University in Pennsylvania and is a licensed civil engineer. (Muskivitch Expert Report ¶¶ 3, 4.) He is currently the Manager of the Mechanical Simulations Group for Pacific Consultants, L.L.C. in California; in that capacity, he is responsible for directing and conducting mechanical simulations and analysis primarily of medical implantable devices and electronic components. (Id. ¶ 2.)

BSC retained Dr. Muskivitch to conduct a mechanical simulation of the deployment and redeployment of the nitinol vena cava filters described in the Cragg II article in order to determine whether stress-induced martensite formed

in the filter when it was withdrawn into the catheter in vivo and redeployed. Dr. Muskivitch analyzed the Cragg publication and performed an FEA for the nitinol vena cava filter described therein. (Muskivitch Expert Report, App. B.)

Dr. Muskivitch asserts in his report that "[t]he level of strain in the nitinol material and its temperature are used to determine whether the nitinol is martensite or austenite." (Muskivitch Expert Report, ¶ 13.) The parameters of the nitinol material model used in the simulations were assumed to represent nitinol which is martensite at 0 C (at which temperature it is described as "soft" in the Cragg II article) and is austenite above 30 C in an unstressed state (in that the Cragg II article identified a "transformation temperature" of approximately 30 C). (Muskivitch Expert Report, App. B ¶ 15)

In addition to the FEA, Dr. Muskivitch had filters manufactured from medical grade stainless steel wire. (Muskivitch Expert Report ¶ 27.) These stainless steel filters had essentially the same dimensions as the nitinol vena cava filters described in the Cragg II article. (Id.) Dr. Muskivitch caused these filters to be drawn into a cylindrical cavity having the same diameter as the catheter used in the Cragg II experiment. Dr. Muskivitch observed that, when the stainless steel filters were drawn into such a cavity, their original shape was destroyed because the material strains on the filters exceeded their elastic limit, causing permanent plastic deformation. (Id. ¶ 28.)

2. Analysis

a. Dr. Bhattacharya

i. Non-infringement

Medtronic argues that Dr. Bhattacharya's methodology in arriving at his conclusion that no stress-induced martensite forms in the RADIUSTM stent is unsound because he never tested an actual RADIUSTM stent product, despite the fact that samples of the product were readily available. Medtronic asserts that courts have "routinely" excluded expert opinion testimony where the expert has not performed actual tests on the device or product about which the expert is going to testify.

The cases relied upon by Medtronic are products liability cases: Pride v. BIC Corp., 218 F.3d 566 (6th Cir.2000); Coffey v. Dowley Manufacturing, Inc., 187 F.Supp.2d 958 (M.D.Tenn.2002); and American Family Insurance Group v. JVC Americas Corp., Civ. No. 00-27 (DSD/JMM), 2001 U.S. Dist. LEXIS 8001 (D.Minn. Apr. 30, 2001). In these cases, the plaintiff's expert witnesses intended to opine as to the likelihood that the product in question behaved in a certain way on a particular occasion and why; exemplars of the product in question were available for testing, but the witnesses did not test their hypotheses using actual items. Pride, 218 F.3d at 571-72; Coffey, 187 F.Supp.2d at 976-77; American Family Ins. Group, 2001 U.S. Dist. LEXIS 8001 at * 11-12. In these cases, due to the failure to test the hypothesis, the court concluded that the proposed testimony was not sufficiently reliable to be admitted into evidence. Pride, 218 F.3d at 577-78; Coffey, 187 F.Supp.2d at 978-79; American Family Ins. Group, 2001 U.S. Dist. LEXIS 8001 at *12.

***16** BSC argues that these cases are distinguishable because Dr. Bhattachaiya had available to him and considered the FEA and inferential tests performed by Medtronic's own expert, Dr. Lagoudas. BSC contends that the results of these tests support Dr. Bhattacharya's opinion that no stress-induced martensite formed in the RADIUSTM stent system during either manufacture or shipping. [FN23] BSC's argument is unpersuasive. In reaching his opinion that the RADIUSTM stent does not, at any time, display stress-induced martensite, Dr. Bhattachaiya relied upon many BSC documents but made no mention of relying on Dr. Lagoudas' test results. (Bhattachaiya Rebuttal Expert Report at 17 n. 13.) In fact, Dr. Bhattachaiya roundly criticized both the FEA and the inferential tests that Dr. Lagoudas performed. Dr. Bhattachaiya pointed out several errors in Lagoudas' FEA, which he contended were significant and rendered the analysis unreliable. After identifying those errors in Dr. Lagoudas' model, Dr. Bhattachaiya opined that the results of the FEA "conclusively demonstrate that the model does not accurately represent what is occurring to the RADIUSTM stent as it is being loaded and deployed." (Bhattacharya Rebuttal Expert Report at 27 (emphasis added).) A model that does not accurately represent what is happening to the RADIUSTM stent cannot provide a reliable and

relevant basis for an opinion as to whether stress-induced martensite formed in that device. As for the "inferential analysis," the Court itself has ruled that Dr. Lagoudas' methodology with respect to those experiments was not sufficiently reliable. If Dr. Lagoudas cannot base an opinion from those measurements, neither can Dr. Bhattacharya.

FN23. From the expert reports of Dr. Lagoudas, it is evident that Medtronic disputes this assertion.

As this Court has already indicated, "[e]ngineering testimony rests upon scientific foundations." Kumho Tire, 526 U.S. at 148, 150. "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed this methodology is what distinguishes science from other fields of human inquiry." Daubert, 509 U.S. at 593 (emphasis added) (quoting E. Green & C. Nesson, Problems, Cases, and Materials on Evidence 645 (1983)). In this case, Dr. Bhattacharya reviewed internal Boston Scientific documents pertaining to the RADIUSTM stent and reviewed an article published (one assumes) by peers in the field of mechanical engineering. From that information, he generated a hypothesis that, after the shape memory alloy stent has been loaded into the restraining catheter, the stress found in the stent system at any given temperature never rises to a level sufficient to form stress-induced martensite. Dr. Bhattacharya did not test that hypothesis against the RADIUSTM stent itself, however, to see if it could be verified, even though exemplar RADIUSTM stent systems were available to him from his own client and/or on the open market. [FN24]

FN24. There is no evidence suggesting that the experiments performed by Madangopal, et al. are at all relevant to the issues before the Court in this infringement action. There is no basis, therefore, for concluding that any experiments by Madangopal, et al., are an adequate substitute for testing the RADIUSTM stent system itself.

BSC does not assert that Dr. Bhattacharya could not test his hypothesis using specimen stents, but rather that he did not have to. (Defs.' Response to Pl.'s Mot. in Limine to Exclude Test. of Defs.' Experts at 18.) Dr. Bhattacharya testified, however, that generally, in his professional practice, it is very common for him to check his analysis against experiments. (Bhattacharya Dep. at 119-20.) Thus, by failing to check his hypothesis regarding the RADIUSTM stent against experiments, Dr. Bhattacharya departed from his usual professional practice. The Court concludes that Dr. Bhattacharya's failure to test or validate his hypothesis, and his apparent departure from the level of intellectual rigor that characterizes his work in his usual professional practice, render his proposed opinion testimony as to whether stress-induced martensite forms in the RADIUSTM stent system inadmissible under Rule 702.

ii. Anticipation by Cragg II

***17** Medtronic contends that the methodology by which Dr. Bhattacharya's reached his opinion that stress-induced martensite forms in the nitinol filters described in the Cragg II article is inadequate because he never tried to replicate what was described in the Cragg II paper to determine whether stress-induced martensite in fact forms. [FN25] BSC responds that Dr. Bhattacharya used well-established mathematical formulae and "conservative" assumptions to arrive at strain calculations ranging between 2% and 4.4% for the filters as they were drawn back into the catheters. Medtronic has not questioned the formulae Dr. Bhattacharya selected and, although it complains that Dr. Bhattacharya lacked certain information about the filters, it does not complain that the values he used in the formulae were incorrect.

FN25. Medtronic criticizes Dr. Bhattacharya for assuming that, when the Cragg II article says the filters were "successfully repositioned," it means that the filters regained their original shape. This argument does not address the heart of Dr. Bhattacharya's analysis, which involves measuring the strain placed on the filter as it is drawn into the catheter, not measuring what happens when the filter is extruded out of the catheter.

Dr. Bhattacharya explained at his deposition why he did not try to replicate the Cragg II filters to test whether stress-induced martensite formed:

I was trying to estimate the amount of strain that was present in these filters as they were deformed from being in the vena cava to inside the catheter, and I wanted to find the most--the surest way that I could make a conclusion that would be beyond any doubt, and therefore I chose the most

> conservative way I knew. I asked what is the strain, the minimum possible strain, that a body would have to suffer as it was being deformed from a conical shape to a shape constrained in a catheter, and that answer turned out to be ... of the order of 3 and 4 percent, so it was so overwhelming. The most conservative question was so overwhelming that there is no doubt that stress-induced martensite was formed, and therefore I did not see any need to replicate these results where one would have to--the--this analysis that I performed, which was the most conservative possible, was so overwhelming that I didn't feel any need to do that.

(Bhattacharya Dep. at 155.) Plaintiff replies that Dr. Bhattacharya's assertion that he did not need to test specimen nitinol vena cava filters is contrary to what Daubert and its progeny say about testing a theory whenever possible. The Court disagrees.

The Initial Expert Report sets out Dr. Bhattacharya's hypothesis, based on the information in the Cragg II paper, that the vena cava filters behaved as they did because stress-induced martensite formed. He then tested that hypothesis by utilizing a generally accepted scientific principle--the formulae that represent the strain generated in a conical helix as it is drawn into a cavity--to calculate the strains placed on the nitinol filters when they were withdrawn into the catheter. The mathematical calculations provided data from which Dr. Bhattacharya then eliminated alternative possible mechanisms for deformation of the filters as they were drawn back into the catheters. BSC has met its burden of establishing the admissibility under Rule 702 of Dr. Bhattacharya's expert testimony concerning the Cragg II vena cava filters.

b. Muskivitch--Anticipation by Cragg II

***18** Medtronic challenges the admissibility of Dr. Muskivitch's expert testimony on the grounds that an FEA, by itself, is not a generally accepted, reliable methodology. Medtronic cites to Dr. Muskivitch's deposition testimony, in which he states that an FEA "is a predictive technique, and it always serves to reinforce the validity of the predictions by actual product behavior, so its just another level of verification that is done in a finite element analysis either with direct tests or with other--other means of predictive engineering." (Muskivitch Dep. at 42-43.) Asked whether, for the FEA of the vena cava filters, he reinforced the validity of the FEA's predictions by actual product behavior, Dr. Muskivitch stated that he had not because he had not been asked to do so. (Id. at 43.) Counsel for Medtronic also asked whether, after Dr. Muskivitch had completed his FEA modeling, it would have been helpful to have been provided a sample of the nitinol material Dr. Cragg actually used for the filter. He answered that it would have been helpful; from the sample, he could have determined whether any of the assumptions made for the FEA model were inaccurate. (Id. at 45-46.) He was told, however, that the filter no longer existed. (Id. at 43.)

BSC responds that, because the "trilinear FEA model" Dr. Muskivitch used has been submitted to the FDA for nitinol medical devices, it is a generally accepted, reliable methodology to model nitinol. BSC further argues that the Cragg II article describes the "experiment," therefore, there is no need to perform additional experiments. [FN26] Medtronic replies that Dr. Muskivitch's testimony establishes that, whenever he has the opportunity, he checks his FEA predictive model against the actual device he is modeling. (Muskivitch Dep. at 42.) Medtronic asserts that Dr. Muskivitch could have checked his FEA by constructing sample nitinol filters like those Dr. Cragg used and attempting to reproduce the procedure described in the article. According to Medtronic, Dr. Muskivitch's departure from his standard practice of verifying an FEA model against the actual device makes his testimony about the FEA performed for BSC unreliable.

> FN26. BSC also argues that Medtronic's expert "admitted" that the Cragg II filters formed stress-induced martensite; therefore, they cannot challenge Dr. Muskivitch's expert opinion on that question. Whether Medtronic's expert believes that stress-induced martensite is present in the Cragg II filters is irrelevant, however, to the issue before this Court--whether the methodology of BSC's experts is sufficiently reliable to make their expert testimony admissible under Rule 702.

The United States District Court for the Middle District of Tennessee has recently considered the very issue presented to this Court by Medtronic's motion: whether an FEA, standing alone, constitutes appropriate validation for proposed expert testimony

under Federal Rule of Evidence 702. The district court observed that "a great deal of finite element analysis concerns theoretical models of objects or systems that do not yet exist." Coffey, 187 F.Supp.2d at 976. This observation is confirmed by Dr. Muskivitch's deposition testimony:

Q: You have agreed that an FEA is a predictive modeling tool.
A: That's correct.
Q: By definition, prediction means that you are working to some extent in theory because you don't have the actual--
A: Uh-huh.
***19** Q: --thing, whatever the thing is; right?
A: Yes.

(Muskivitch Dep. at 41.) The Tennessee district court reasoned that, although Coffey's expert, Dr. Wilson, "undertook to validate his hypothesis by using finite element analysis, he did not utilize actual testing to verify the computerized predictions in a real world setting." Id. at 977 (emphasis added). In Coffey, the defendant's expert demonstrated that the hypothesis advanced by Coffey's expert could be physically tested and verified in the laboratory. Id. at 978. Furthermore, exemplars of the device at issue existed. The Coffey court concluded that a "[b]are finite element analysis, even assuming that it was based on correct assumptions and was an appropriate form of finite element analysis, was not 'appropriate validation' in this context." Id. at 977-78 (emphasis added).

This Court agrees with the Coffey court's observation that context is vitally important in determining whether a given methodology is "appropriate validation." In this case, the context for evaluating the sufficiency of an FEA is different from that presented in Coffey. It is unclear that exemplars of Dr. Cragg's nitinol vena cava filters are available. Furthermore, Medtronic's expert, Dr. Lagoudas, has not demonstrated that the hypothesis advanced by Dr. Muskivitch could be physically tested and verified in the laboratory. Dr. Muskivitch's hypothesis was that measuring the level of strain in the nitinol material and its temperature would allow one to determine whether the nitinol is in a martensitic state or an austenitic state. [FN27] (Muskivitch Expert Report ¶ 13.) Dr. Lagoudas never measured or calculated the level of strain present in the nitinol filters he had fabricated. [FN28] Medtronic has not established that the reasoning in Coffey applies to the FEA that Dr. Muskivitch used to validate his hypothesis. [FN29]

FN27. Dr. Muskivitch's FEA calculated the strain level in the filter at various point in the deployment-reloading-redeployment process described in the Cragg II article. (Id. ¶¶ 19, 22, 25 & App. A, figs. 5(a)-(c), 7(a)-(c), 9(a)-(c).) From these calculations, the FEA estimated which parts of the filter would be austenite and which parts would be martensite. (Id. ¶¶ 20, 23, 26, & App. A, figs. 6(a)-(c), 8(a)-(c), 10(a)-(c).)

FN28. Instead, Dr. Lagoudas had the filters loaded into catheters and deployed at different temperatures. (Lagoudas Rebuttal Report, App. at 1.) After each filter was deployed, Dr. Lagoudas visually compared the extent of shape recovery presented by the filter. Dr. Lagoudas also observed that, when the filter was loaded at body temperature or was "constrained by hand" from rotating as it was loaded, the "pulling force" required to load the filter was greater than that required to load the filter unconstrained at 1 C. (See id. at 1-3.) Yet, he never measured or calculated the level of strain in the filters.

FN29. BSC acknowledged at the hearing on the motions in limine that it chose not to bring a motion to exclude Dr. Lagoudas' FEA analysis but chose not to do so. (Hrg. Tr. at 27.) Were BSC to bring a belated motion to exclude Dr. Lagoudas' FEA under Coffey, on the grounds that evidence regarding the laboratory experiments Dr. Lagoudas performed on specimen RADIUSTM stents has been excluded, such a motion would also be distinguishable from Coffey. BSC's infringement expert, Dr. Bhattacharya, has not demonstrated that the hypothesis advanced by Dr. Lagoudas can be physically tested and verified in the laboratory. Indeed, as discussed above, Dr. Bhattacharya has done no laboratory experiments with exemplar RADIUSTM stent systems.

Medtronic also attacks Dr. Muskivitch's FEA analysis as being unreliable on the grounds that he made numerous unsubstantiated assumptions about the Cragg II nitinol filters in order to prepare his FEA model. Many of these assumptions, Medtronic argues, were made because the Cragg II article provides little information about the nitinol used to make the filters. For example, Dr. Muskivitch assumed that the composition of the nitinol Dr.

Cragg had used was "a 50/50 alloy between nickel and titanium." (Muskivitch Dep. at 90-91.) He also assumed the critical transformation temperatures--M F , M S , A S , and A F --for the alloy, and its "stress-strain" curves. In addition, he assumed that, above a 2% strain level, any martensite created was stress-induced martensite. (Id. at 275.)

BSC acknowledges that Dr. Muskivitch assumed a stress-strain curve for his model, but contends that the curve chosen was a "reasonable" choice, in that it was one his company has used when modelling nitinol medical devices for submissions to the FDA. Dr. Muskivitch testified that he chose a stress-strain curve used "for other medical implantable devices that exhibit stress-induced martensite" and are deployed in the body. (Muskivitch Dep. at 155 (emphasis added).) Dr. Muskivitch described his approach as being a strain based approach, in which

> ***20** we made certain assumptions about the--the stress-strain behavior of the material itself, and by determining what strain level we were at we could determine whether or not--or where on the stress-strain curve the particular point in the material was and then we could determine whether or not it was austenitic or martensitic.

(Id. at 77 (emphasis added).)

Therein lies a problem. According to Dr. Muskivitch, the stress-strain curve is important for determining whether the alloy in the filter is in an austenitic or a martensitic state. Dr. Muskivitch has assumed a stress-strain curve for an alloy that exhibits stress-induced martensite. He did not, however, know the composition of the nitinol used or how that alloy was processed. Dr. Muskivitch testified that "[i]f the processing history is known with the--the different temperature, the different transformation temperatures, and we have a--a stress-strain curve provided by the material supplier, then we are--the analysis will be more reliable ." (Id. at 48-49 (emphasis added).)

From Dr. Muskivitch's testimony, therefore, there appear to be several stress-strain curves applicable to nitinol-not just one. The record establishes that the composition of nitinol can vary greatly (see, e.g., '957 patent, col. 4, ll. 30-53), [FN30] and not all nitinol compounds display stress-induced martensite at temperatures near human body temperature. Dr. Muskivitch acknowledged that having the correct stress-strain curve for the nitinol alloy being modeled makes the FEA analysis more reliable, there is no evidence, however, that the stress-strain curve he assumed for his FEA bears any relationship, let alone a close one, to the curve that actually applies to the nitinol used for the vena cava filters.

> FN30. Nitinol describes "a group of shape-memory alloys that are intermetallic compounds of nickel and titanium, having good fatigue properties." See Harcourt Academic Press Dictionary of Science & Technology, <www.harcourt.com> (emphasis added) (2002).

The Court has serious reservations concerning Dr. Muskivitch's assumption that the nitinol used for the vena cava filters was "a 50/50 alloy between nickel and titanium." (Muskivitch Dep. at 90-91.) Although Dr. Muskivitch acknowledged that other trace metals could be present in nitinol (id. at 91), he apparently did not factor their presence into his FEA model. The transformation temperature data for the nitinol alloys disclosed in U.S. Patent No. 4,505,767 demonstrates that a change in the atomic composition of nitinol by as little as less than one percent can make a significant difference in the transformation temperatures of the alloy. [FN31] ('957 patent, col. 4, ll. 30-53.) Thus, even though Dr. Muskivitch selected a "standard" nitinol alloy, there is not sufficient evidence to suggest that the "standard" has any meaningful relationship to the alloy actually used for the vena cava filters. BSC has not established that Dr. Muskivitch's assumptions about the alloy's composition were reasonable.

> FN31. Compare the transformation temperatures for an alloy comprised of 50% nickel, 46% titanium and 4% vanadium (M S of -11 C and A (90) of 7 C) with the transformation temperatures for an alloy comprised of 49.5% nickel, 46% titanium, and 4.5% vanadium (M S of 6 C and A (90) of 35 C).

Finally, Medtronic objects to the admission of testimony or other evidence regarding experiments that Dr. Muskivitch conducted involving the loading and deploying of spiral filters made from stainless steel wire. Medtronic argues that these experiments are irrelevant to any issue presented in the case and should be excluded under Rules 402 and 403. The Court concludes that, even if there is some relevance to the experiments done with the stainless steel

filters, their minimal probative value is substantially outweighed by the likelihood of confusion of the issues and concerns about undue delay and wasting time on evidence that does not bear directly on the issues presented by BSC's invalidity defenses.

***21** The Court concludes that BSC has not satisfied their burden of establishing the reliability of Dr. Muskivitch's FEA in light of the assumptions he made to establish his model. Furthermore, BSC has not established that Dr. Muskivitch's FEA is sufficiently connected to the facts of the actual Cragg II experiments so as to be relevant to the jury's inquiry on BSC's invalidity defenses. In addition, the Court concludes that evidence regarding Muskivitch's stainless steel filter experiments is inadmissible under Rule 403. Accordingly, the Court will exclude the testimony of Dr. Muskivitch in its entirety.

E. Medtronic's Motion to Exclude Testimony from Certain Employees of BSC

Medtronic moves to preclude the admission of opinion testimony from certain employees of Boston Scientific and SciMed to the extent that BSC has not complied with the expert disclosure requirements of the Federal Rules of Civil Procedure. Specifically, Medtronic objects to these employees offering expert testimony under Federal Rules of Evidence 701 and 702 on the issue of whether stress-induced martensite forms in the RADIUSTM stent system. BSC responds that employees who do not regularly testify for the employer but are doing so in a particular case do not need to provide the written report required by Rule 26 of the Federal Rules of Civil Procedure. Furthermore, BSC claims, these witnesses will be testifying as to facts about which they have first-hand knowledge.

The basis for Medtronic's motion is the current version of Federal Rule of Evidence 701, which defines the permissible scope of lay opinion testimony. [FN32] Rule 701 provides as follows:

> FN32. The Supreme Court's April 17, 2000 Order regarding the 2000 amendments to the Federal Rules of Evidence provides that those amendments "shall take effect on December 1, 2000, and shall govern all proceedings thereafter commenced and, insofar as just and practicable, all proceedings then pending." BSC has not seriously argued that it would be unjust or impracticable for the 2000 amendments to apply to this case. In fact, BSC itself cited the 2000 version of Rule 702 as the standard for evaluating the admissibility of expert testimony. (See Defs.' Mem. in Support of Mot. to Exclude Test. of Dr. Lagoudas at 18.)

> If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

Fed.R.Evid. 701 (2001) (emphasis added). The purpose of the 2000 amendment to Rule 701 was "to eliminate the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing." Fed.R.Evid. 701, advisory committee's note (2000).

BSC asserts that "Brown and other SCIMED employees are fact witnesses testifying to occurrences within their own personal knowledge and experience." (Defs.' Mem. in Response to Pl.'s Mot. in Limine to Exclude Test, of Defs.' Employees at 3.) Specifically, BSC argues that Brian Brown, who was the project manager for the development of the RADIUSTM stent system,

> has detailed factual knowledge concerning the operation of the RADIUSTM stent. In fact, he has first-hand knowledge, obtained in the course of his ordinary job duties, concerning some of the most important issues in this case, i.e., the formation of austenite in the RADIUSTM stent and whether [stress-induced martensite] is present in the stent at any point. [FN33]

> FN33. BSC has indicated that both Luke Dohmen and Scott Bluni have first-hand knowledge regarding "the infringement or non-infringement of the patents-in-suit by the RADIUSTM stent." (Defs.' Mem. in Response to Pl.'s Mot. in Limine to Exclude Test. of Defs.' Employees at 7.) BSC observes that Medtronic did not choose to depose these individuals; therefore, they cannot be heard to complain that they are prejudiced by "unknown" testimony. (Id.) ***22** (Id.) BSC distinguishes Brown from the employees discussed in Minnesota Mining

& Manufacturing Co. v. SignTech, U.S.A. Ltd., 177 F.R.D. 459 (D.Minn.1998) (Lebedoff, Mag. J.). The 3M employees in Signtech were required to comply with the expert disclosure requirements of Rule 26(a)(2) because they were not testifying "as fact or hybrid fact/expert witnesses." 177 F.R.D. at 461. BSC argues that the only category of "employee-experts" who must submit expert reports are those who regularly testify. (Defs.' Mem. in Response to Pl.'s Mot. in Limine to Exclude Test, of Defs.' Employees at 2 (quoting Navaho Nation, v. Norris, 189 F.R.D. 610, 612-13 (E.D.Wash.1999).) BSC claims that, because Brown and the other employees identified in their brief--Luke Dohmen and Scott Bluni--do not regularly testify on behalf of their employer, they are not required to supply written expert reports.

BSC's analysis of 3M v. SignTech and Navaho Nation is not persuasive. The distinction drawn by the magistrate judge in 3M between "fact or hybrid fact/expert witnesses" and "expert witnesses" appears to run counter to the evidentiary rules on expert testimony. Rule 701 "does not distinguish between expert and lay witnesses, but rather between expert and lay testimony . " Fed.R.Evid. 701, advisory committee's note (2000). Thus, "any part of a witness' testimony that is based upon scientific, technical, or other specialized knowledge within the scope of Rule 702 is governed by the standards of Rule 702 and the corresponding disclosure requirements of the Civil ... Rules." Id.

To determine whether proposed testimony is expert testimony, one turns to Rule 702 of the Federal Rules of Evidence, which states that a witness who is "qualified as an expert by knowledge, skill, experience, training, or education" may testify to "scientific, technical or other specialized knowledge" in the form of opinion or otherwise where such knowledge "would assist the trier of fact to understand the evidence or to determine a fact in issue." The formation of austenite and the presence of stress-induced martensile in the RADIUSTM stent are not facts that can be perceived with the five senses; those facts must be inferred. Brown has clearly formed opinions and/or drawn inferences regarding the formation of austenite and the presence of stress-induced martensite in the RADIUSTM stent based upon the specialized knowledge of shape metal alloys he has gained through his training, experience, and/or education. It is evident to the Court that receiving scientific, technical, or other specialized knowledge would help the jury determine whether stress-induced martensite is present at any time in the RADIUSTM stent system. Brown's proposed testimony regarding the formation of austenite and the presence of stress-induced martensite, therefore, falls within the scope of Rule 702.

Rule 26(a)(1) of the Federal Rules of Civil Procedure requires a party to disclose "the identity of any person who may be used at trial to present evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence." [FN34] Fed.R.Civ.P. 26(a)(1) (emphasis added). In addition to identifying potential witnesses who may testify as to scientific, technical, or other specialized knowledge, by opinion or otherwise, Rule 26(a)(2) provides that, "with respect to a witness who is retained or specially employed to provide expert testimony in the case or whose duties as an employee of the party regularly involve giving expert testimony," the party must also provide a written report regarding the witness's expert testimony. Fed.R.Civ.P. 26(a)(2) (emphasis added).

FN34. Thus, Rule 26(a)(1) mirrors the same distinction between expert testimony and lay testimony as is made in Rules 701 and 702. The application of Rule 26(a)(1) does not depend upon whether the individual is an expert witness or a lay witness.

***23** BSC's claim that Brown need not provide an expert report under Rule 26(a)(2) because he does not regularly give expert testimony is not persuasive. The argument construes only half of the rule and does not address whether Brown has been "retained or specially employed" to give expert testimony. As another district court has observed, "[a]n employee is 'employed' when she is 'put to use or service.' ... The adverb 'specially' is 'used with reference to a particular purpose' that is 'surpassing what is common or usual.' " KW Plastics v. U.S. Can Co., 199 F.R.D. 687, 690 (M.D.Ala.2000) (quoting The American Heritage Dictionary). Furthermore, "when a corporate party designates one of its employees as an expert, it typically authorizes the employee to perform special actions outside of the employee's normal scope of employment." Id. Accepting BSC's assertion that Brown does not usually present expert testimony at

trial for his employer, the Court finds that Brown's service in this case would be "special." BSC has "specially employed" Brown to present expert testimony on their behalf. Therefore, to the extent Brown would testify to opinions or inferences that are based on "scientific, technical or other specialized knowledge"--including opinion or inferential testimony as to whether stress-induced martensite forms in RADIUSTM stent system--BSC was required to provide the required Rule 26(a)(2) written report setting forth the substance of and bases for Brown's opinion testimony.

BSC argues that Medtronic cannot claim either prejudice or surprise from any failure to comply with the expert disclosure requirements of Rule 26 because Medtronic thoroughly explored the bases for Brown's opinions and beliefs at deposition. BSC, however, identified Brown as someone who would testify on behalf of the corporate Defendants in response to Medtronic's 30(b)(6) deposition notice. (Def.'s Mem. in Response to Pl.'s Mot. in Limine to Exclude Test. of Defs.' Employees at 5-6.) Their argument disregards the role Brown occupied when testifying. He was not deposed in his individual capacity, but rather as the corporations' Rule 30(b)(6) designee. The opinions Medtronic explored were not Brown's individually, but rather those of BSC, for which he was simply a designated representative.

BSC contends that their employees' testimony is relevant to the issue of willful infringement in that they have "actual knowledge regarding [BSC's] beliefs and experiences that its product does not infringe Medtronic's patents." (Id. at 1.) BSC asserts that they are "entitled to present evidence regarding [their] good faith actions prior to and during the launch of the RADIUSTM stent and [their] reasonable beliefs that [their] product did not infringe Medtronic's patents." (Id. at 4.) Medtronic replies that evidence introduced on the issue of willful infringement must be competent and admissible. (Medtronic's Reply Mem. at 4.)

***24** Ultimately, the Court agrees with BSC's argument, made at the motion in limine hearing, that the admissibility of their witnesses' testimony should not be judged in a vacuum. (Hrg. Tr. at 71.) Therefore, the Court directs BSC to submit--by August 19, 2002--a detailed written offer of proof describing the facts as to which each employee-witness proposes to testify and the witness's competence to testify to those facts. Upon reviewing that offer of proof, the Court will determine whether the witnesses' testimony is relevant and admissible.

II. Motions Relating to Damages

A. BSC's Motion to Exclude Testimony About the Raychem Bundle

BSC moves to exclude from the trial all evidence concerning the price of, offers for, or valuations of the property rights Medtronic purchased from Raychem (including the patents-in-suit) in 1996. Specifically, BSC contends contend that (a) under Federal Rules of Evidence 702 and 703, Medtronic's damages expert, Robert Goldscheider, must be precluded from relying on or testifying about any price of, offer for, or valuation of the Raychem bundle, and (b) under Federal Rules of Evidence 402 and 403, Medtronic must not be allowed to present any evidence of the value, price, or offers for the Raychem bundle. The Court has ruled that Mr. Goldscheider cannot testify about what portion of the price Medtronic paid for the Raychem bundle is attributable to the patents-in-suit, nor will he be allowed to opine that the price Medtronic paid for the Raychem bundle supports the imposition of a high reasonable royalty rate. (See, supra, section I.B.) The Court therefore turns to BSC's broader argument that all evidence pertaining to Medtronic's purchase of the Raychem bundle, and Boston Scientific's offers therefor, should be excluded.

The "Raychem bundle" consisted of thirteen issued United States patents, twenty issued foreign patents, fourteen pending foreign patent applications, eleven United States patent applications, seventy invention disclosures, licenses, and other tangible rights. (Patent Assignment Agreement between Raychem Corp. & Medtronic, Inc. at MED004727-004730.) Medtronic bought the "Raychem bundle" in August 1996 for approximately $25 million. Prior to that purchase, BSC apparently made a written offer to purchase the portfolio for $15 million, followed by an oral offer of $30 million. At the time Medtronic purchased the Raychem bundle, one of the two patents-in-suit had already been issued and the application for the other patent was still pending.

Medtronic argues that the price paid for the Raychem bundle and the offers BSC made to purchase that portfolio are relevant to two issues: damages and willfulness. With respect to damages, Medtronic points out that BSC's own damages expert, Alan Friedman, mentioned in the "basis and reason for opinion" section of his report that Medtronic had paid $25 million to Raychem for the "Raychem bundle." (See Responsive Expert Report of Alan Friedman ¶ 6.) Medtronic also asserts that BSC's offer to buy the "Raychem bundle" for $30 million is relevant to a reasonable royalty analysis because BSC's "willingness to pay $30 million outright is evidence of what BSC would have been able to afford to pay as a royalty if it had negotiated a license at the time infringement began." (Medtronic's Mem. Opp'n to Mot. in Limine to Exclude Evid. Re: Raychem Bundle at 12.) In support of this relevance argument, Medtronic relies on Century Wrecker v. E.R. Buske Manufacturing Co. ., 898 F.Supp. 1334 (N.D.Iowa 1995).

***25** At issue in Century Wrecker was whether "evidence of an alleged infringer's financial condition, profitability, or ability to pay a particular royalty figure is relevant and admissible." 898 F.Supp. at 1338. The Court concluded that such evidence was relevant and admissible but may be entitled to very little weight in determining what is a "reasonable royalty." Id. In the present case, if infringement were established, the hypothetical negotiations for a "reasonable royalty" would have taken place in July 1998, when BSC began manufacturing and marketing the RADIUSTM stent system. Medtronic offers no basis, either in law or in fact, for concluding that BSC's willingness to pay $15 million or $30 million in August 1996 has any bearing on the ability to pay a given royalty in July 1998. Century Wrecker does not support Medtronic's argument; evidence of BSC's offers to Raychem is not relevant to the issue of damages.

With respect to whether BSC's conduct was willful, Medtronic contends that a reasonable jury could infer from the fact that BSC offered to purchase the "Raychem bundle" for $15 million and later for $30 million that BSC believed the patents-in-suit to be valid and enforceable. BSC's belief that the patents-in-suit are valid and enforceable is relevant, Medtronic contends, to the willfulness of BSC's conduct. In support of this argument, Medtronic cites to the following sentence in Boston Scientific's Executive Summary: "Patent counsel believes it is most likely the patents [including patents issued to Jervis] will prove to be strong and enforceable." (Medtronic's Mem. Opp'n to Mot. in Limine to Exclude Evid. Re: Raychem Bundle at 7 (quoting Executive Summary at BSC 055670).)

Willful infringement is established where the patentee proves that the alleged infringer (a) was aware of the patent and (b) failed to exercise due care to determine whether or not the patents was not infringed or invalid. Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1583 (Fed.Cir.1996). Thus, a party who has actual knowledge of a patent but does not have a reasonable basis for reaching a good faith conclusion that the patent was either not infringed or invalid may be liable for willful infringement. Id. The 1996 offers to purchase the Raychem portfolio are relevant to a willfulness analysis in that they evidence BSC's knowledge of at least one of the patents-in-suit. [FN35] The potential prejudice asserted by BSC if such evidence is admitted at trial is mitigated by the fact that the Court has already concluded that Medtronic may not present evidence to the effect that the "flagship rights" in that portfolio were the patents-in-suit, or that the "primary value" of the portfolio is attributable to the patents-in-suit.

FN35. Medtronic's contention that Boston Scientific was willing to offer substantial sums to purchase the Raychem bundle after receiving an opinion from Kenyon & Kenyon lacks support in the record. During a 30(b)(6) deposition of the Defendant corporations, Frank Grillo testified that he believed a quick oral validity analysis had been done of the patents in the Raychem portfolio by the Kenyon & Kenyon law firm. (Grillo Dep. at 66-67.) The deposition excerpt presented to the Court, however, does not indicate when this analysis was done, let alone establish that it was done prior to Boston Scientific's offers to purchase the Raychem portfolio. (See id.) Nevertheless, Medtronic asserts that the Kenyon & Kenyon validity analysis influenced the drafting of the August 8, 1996 Executive Summary regarding the possible purchase of the Raychem bundle. (Medtronic's Mem. Opp'n to Mot. to Exclude Evid. Re: Raychem Bundle at 7.) The Executive Summary does not, however, identify the patent counsel to which it is referring, let alone state that it is Kenyon & Kenyon.

The Court concludes that it is relevant to the jury's understanding of this case for evidence to be received establishing that Medtronic purchased the patents-in-suit from Raychem in 1996 as part of a larger acquisition of intellectual property rights. The Court also concludes that it is relevant and not unduly prejudicial for the jury to receive evidence establishing that the purchase price for the entire Raychem portfolio of intellectual property rights was $25 million. Finally, the Court concludes that Boston Scientific's written offer of $15 million and its subsequent oral offer of $30 million for the same bundle of intellectual property rights are not relevant to the issues of damages but are relevant to the issue of willfulness. The motion will therefore be granted in part..

B. Defendants' Motion to Exclude Royalty Rates Negotiated by Medtronic in Settling other Lawsuits

***26** Medtronic has settled unrelated litigation with Johnson and Johnson and Cordis Corporation in which, as part of the agreement, Johnson & Johnson/Cordis agreed to pay a royalty rate for a group of intellectual property rights including the patents in suit. The settlement royalty rate involves a variety of technologies; the patents-in-suit are two of the 15 "royalty bearing licensed patents ." Medtronic's damages expert, Goldscheider, has apparently opined that the royalty rate negotiated with Johnson & Johnson/Cordis, who is a major competitor of Medtronic, is relevant to a damages analysis because their settlement negotiations parallel hypothetical negotiations with BSC.

BSC argues that the royalty rate in that settlement came from complicated and unique circumstances that have nothing to do with hypothetical negotiations for a reasonable royalty under Georgia Pacific Corp. v. U.S. Plywood Corp., 318 F.Supp. 1116 (S.D.N.Y.1970). BSC contends that Goldscheider's analysis is contrary to established case law, citing Rude v. Westcott, 130 U.S. 152, 9 S.Ct. 463, 32 L.Ed. 888 (1886). BSC also argues for exclusion of the Johnson & Johnson/Cordis royalty rates under Rule 408 of the Rules of Evidence and Deere & Co. v. Int'l Harvester, Inc., 710 F.2d 1551 (Fed.Cir.1983). Furthermore, BSC contends, the negotiated royalty rate is either irrelevant under Rule 402 or, if relevant, is more prejudicial than probative under Rule 403.

Medtronic does not oppose BSC's motion. Its agreement to concede to the motion is conditioned, however, upon the Court entering an Order precluding all parties from offering or eliciting documents or testimony related to the royalty rate agreed upon in the Johnson & Johnson/ Cordis settlement. Medtronic argues that BSC should not be able to cross-examine Goldscheider on issues related to the Johnson & Johnson royalty rate if he is precluded from defending his reliance upon it in arriving at his expert damages opinion. BSC has not responded to Medtronic's proposed condition.

The Johnson & Johnson/Cordis royalty rate shall be excluded from evidence on several grounds, including Rules 402, 403, and 408 of the Rules of Evidence. The Court finds no relevance of the settlement negotiations to a damages analysis under Georgia Pacific, or, if such relevance exists, its minimal probative value is outweighed by the potential for needless distractions of the jury from the principal issues of the case at hand, which are legion. Neither party shall present evidence relating to the Johnson & Johnson/Cordis settlement or the negotiated royalty rate that was a part of it. That prohibition includes opinion or inferential testimony derived from either the negotiated royalty rate or the facts surrounding those negotiations. [FN36]

> FN36. Thus, to the extent Medtronic's damages expert intends to testify at trial about the Johnson & Johnson/Cordis negotiations, he may not do so.

C. Defendants' Motion to Exclude Testimony about BSC's Relationship with Medinol Ltd.

In October 1995, Boston Scientific entered into a joint venture relationship with Medinol, Ltd., pursuant to which Medinol manufactures and sells to Boston Scientific a stainless steel, balloon-expandable coronary stent that Boston Scientific in turn markets and sells. (Responsive Expert Report of Alan Friedman ¶ 24.) As part of that agreement, Boston Scientific agreed to pay Medinol a royalty on all of the coronary stent products it sells, including those products that were not dependent on Medinol's technology, such as the RADIUSTM stent system.

***27** In April 2001, Medinol sued Boston Scientific and two of its senior officers, alleging breach of contract, breach of fiduciary duty, fraud,

misrepresentation, misappropriation of trade secrets, unjust enrichment, and violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") (hereinafter, "the Medinol lawsuit"). (See June 7, 2001 Aff. of Renee Jackson, Ex. J.) BSC moves to preclude Medtronic from presenting any evidence relating to the Medinol lawsuit on the grounds that such evidence is irrelevant. Medtronic has indicated that it has no intention of offering any evidence relating to the Medinol lawsuit. (Medtronic's Partial Opp'n at 1.) Based on Medtronic's representations, the Court concludes that the portion of BSC's motion relating to the Medinol lawsuit is moot.

Regarding the balance of the motion, BSC concedes that the terms of the 1995 joint venture agreement are themselves relevant. (Defs.' Mem. Supp. Mot. in Limine to Exclude Evid. Re: Medinol Relationship at 1.) BSC seeks to limit the evidence presented at trial regarding its relationship with Medinol strictly to the terms of the agreement. Under Rules 402 and 403 of the Federal Rules of Evidence, they move to preclude Medtronic from presenting any other documents or testimony related to Boston Scientific's day-to-day relationship with or business strategies regarding Medinol.

Medtronic responds that it is entitled to elicit testimony from its damages expert, Robert Goldscheider, that relates to and goes beyond the terms of the Medinol agreement. In his supplemental expert report, Goldscheider concluded that "Boston Scientific's onerous relationship with Medinol" contributed to Boston's Scientific's diminished performance with respect to the RADIUSTM stent. (Goldscheider Supplemental Expert Rep. ¶ 6 .) Goldscheider opined that "[h]ad it not been for [its royalty] payments to Medinol, Boston Scientific's net profit would have been significantly higher, justifying a higher royalty to Medtronic as being reasonable." (Id.) Relying on internal Boston Scientific documents, Goldscheider also concluded that, by 1999, the company had recognized that its relationship with Medinol was hampering its ability to become a market leader in coronary stents. (Id.)

Medtronic argues that the "harshness" of the Medinol agreement is relevant to its damages analysis and to Medtronic's claim that BSC willfully infringed the patents-in-suit. With respect to the damages analysis, Medtronic contends that the substantial amount of the royalty payments to Medinol on the RADIUSTM stent product and Boston Scientific's desperation or "intense desire" to enter the stent market should be considered in connection with the "hypothetical negotiation" analysis set forth in Georgia Pacific Corp. v. U.S. Plywood Corp., 318 F.Supp. 1116 (S.D.N.Y.1970). The Federal Circuit has explained that the royalty rate for damages under § 284

> may be based upon an established royalty, if there is one, or if not, upon the supposed result of hypothetical negotiations between the plaintiff and defendant.... The hypothetical negotiation requires the court to envision the terms of a licensing agreement reached as the result of a supposed meeting between the patentee and the infringer at the time infringement began.

***28** Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1554 (Fed.Cir.1995). In the hypothetical negotiation, the alleged infringer is assumed to be a "prudent licensee"; that is, one who desires to obtain a license to manufacture and sell a particular article embodying the patented invention, paying a royalty to the patent holder and yet still being able to make a reasonable profit. Georgia Pacific, 318 F.Supp. at 1120.

BSC replies that consideration of the royalty payments that Boston Scientific makes to Medinol for RADIUSTM stent sales is an accounting issue; characterizing the Medinol agreement as "harsh" or "onerous" is irrelevant to the "hypothetical negotiation" analysis of Georgia Pacific. BSC further complains that there is no evidentiary basis for Goldscheider's assertion that Boston Scientific was "desperate" to enter the coronary stent market. Finally, BSC points out that the Medinol agreement was entered into in 1995, while the decision to market the RADIUSTM stent came almost three years later. Thus, whatever motivation there was to enter into the Medinol agreement is too remote, temporally, to be relevant to a "hypothetical negotiation" between Medtronic and Boston Scientific in 1998.

The Court concludes, from reviewing Goldscheider's expert reports, that he has offered no factual basis for his assertion that the Medinol agreement is "harsh" or "onerous" or came into being "at a time at which Boston Scientific was desperate for stent technology." (Goldscheider Supplemental Expert Rep. ¶ 6.) Those opinions are no more than the ipse dixit of the witness.

Furthermore, any inferential or opinion testimony about Boston Scientific's corporate state of mind in 1995 regarding the coronary stent market--such as "desperation" or "intense desire"--has, at most, marginal relevance to a "hypothetical negotiation" for a license agreement in 1998, but is likely to involve a substantial digression into an issue that is tangential to the principal questions of fact in the case. Therefore, under Federal Rules of Evidence 402, 403, and 702, documents and testimony regarding Boston Scientific's day today relationship with or business strategies regarding Medinol are inadmissible to establish the "harshness" of the terms of the Medinol agreement and Boston Scientific's "desperation" or "intense desire" to enter the stent market in 1995.

For the same reasons, the Court concludes that evidence regarding Boston Scientific's relationship with Medinol and its business strategies with respect to Medinol are not relevant to the issue of willful infringement or, if relevant, present substantial concerns under Rule 403. Medtronic argues that the "onerous" nature of the Medinol agreement "is evidence of the market pressures and urgency faced by BSC and is, therefore, relevant to Medtronic's willfulness claim." (Medtronic's Opp'n Mem. at 5.) Even if Boston Scientific felt pressure to enter the coronary stent market in 1995, however, Medtronic has not shown how those circumstances in 1995 are relevant to Boston Scientific's conduct in 1998, when the alleged infringement began. The Court will grant BSC's motion to exclude evidence concerning Boston Scientific's day-to-day relationship with, or business strategies regarding, Medinol.

***29** Goldscheider's analysis in his supplemental expert report focused on the impact of the Medinol agreement on the profitability of the RADIUSTM stent product. To the extent he would testify at trial about the impact of the Medinol agreement on the RADIUSTM stent's profitability for Boston Scientific, such testimony satisfies the requirements of Rules 702 and 703, is relevant to a "hypothetical negotiation" analysis and is admissible.

D. Medtronic's Motion to Exclude Testimony of BSC's Damages Expert

BSC identified Alan Friedman as an expert witness who will testify on the issue of damages. Friedman provided an expert report setting out his opinions regarding the reasonable royalty to which Medtronic is entitled if the RADIUSTM stent system is found to infringe the patents-in-suit. Among the bases and reasons for his opinion, Friedman indicated that

> Boston Scientific believed, in early 1998, that it had available to it a non-infringing alternative to the patents-in-suit. In 1996, 1997, and 1998, Boston Scientific received opinions from patent counsel that the Radius stent does not infringe the patents-in-suit. The use of the non-infringing alternative resulted in a cardiovascular stent with the same performance, and was equally acceptable to Boston Scientific's customers.

(Responsive Expert Report of Alan Friedman, ¶ 10.)

Medtronic moves to exclude any testimony from Friedman regarding BSC's belief that the RADIUSTM stent was a non-infringing alternative. Medtronic cites Federal Rule of Evidence 703, which provides that

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted. Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect.

Fed.R.Evid. 703. Medtronic argues that, because Friedman's comments about BSC's belief as to whether the RADIUSTM stent was a non-infringing alternative constitutes inadmissible hearsay under Rules 801 and 802, he may not testify to BSC's belief at trial under Rule 703. In any event, Medtronic contends that BSC's belief that the RADIUSTM stent was a non-infringing alternative is irrelevant to a "reasonable royalty" analysis under Georgia Pacific and therefore inadmissible.

BSC responds that the "value added by the patent" is a relevant consideration to a hypothetical negotiation for a "reasonable royalty" under Georgia Pacific. It argues that a patented invention has only

"limited added value" where the ability to market nonp-infringing alternatives exists. Such a "limited added value" puts the infringement defendant in a better position to negotiate for a lower royalty rate. Therefore, because BSC believed that the RADIUSTM stent was a non-infringing alternative to the patented invention, it would have believed (in a hypothetical negotiation) that the ability to practice the disclosed invention added little value to the proposed license.

***30** To support the admissibility of Friedman's testimony, BSC relies on Zygo Corp. v. Wyko Corp., 79 F.3d 1563 (Fed.Cir.1996). In that case, Wyko manufactured a model of interferometer, called "the Wyko 6000," that was accused of infringing a patent held by Zygo. Wyko had stopped marketing another, non-infringing model of interferometer, called "the SIRIS," when it began selling the Wyko 6000. Zygo, 79 F.3d at 1571. In reviewing Wyko's appeal from the damages award, the Federal Circuit observed that "the fact that Wyko COULD have continued marketing the SIRIS is a factor relevant to the determination of a proper royalty during hypothetical negotiations." Id. (emphasis in original). The court of appeals reasoned that "Wyko would have been in a stronger position to negotiate for a lower royalty rate knowing it had a competitive non-infringing device 'in the wings.' " Id. at 1571-72. The trial court therefore was to "reconsider its award of a 25% royalty rate in light of Wyko's ability to market the noninfringing SIRIS in lieu of marketing the infringing Original Wyko 6000." Id. at 1572.

The Zygo decision is distinguishable from this case. The testimony that Friedman proposes to give, and that Medtronic seeks to exclude, is not about whether BSC has a non-infringing product other than the accused device waiting "in the wings." Rather, Friedman's testimony assumes that an infringer's belief that the accused product does not infringe is relevant to assessing the infringer's negotiating position during hypothetical negotiations. That is not the issue in Zygo, and the Court has found no other case that so holds. The Court will therefore grant Medtronic's motion.

III. Miscellaneous Motions

A. Medtronic's Motion to Exclude Testimony from the Cragg II Paper Authors

Dr. Andrew Cragg and several other doctors in the Department of Radiology at the University of Minnesota Hospitals began working with nitinol in the summer of 1982. Initially, they worked on a nitinol coil stent graft designed to prop open arteries. In April 1983, Cragg and five others (including Gunnar Lund, M.D. and Joseph Rysavy) published an article describing a non-surgical method for placing the arterial grafts into a subject (the "Cragg I paper"). [FN37] That paper described the development of a "new type of endoprosthesis, constructed of a thermal shape memory alloy (nitinol), which can be readily passed through a catheter."

FN37. Andrew Cragg, et al., "Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire," 147 Radiology 261-63 (Apr.1983) (attached as Ex. 24 to the Aff. of Paul J. Robbennolt ("Robbennolt Aff.")).

In September 1983, Cragg and six others from the Radiology Department at the University of Minnesota Hospitals (again, including Dr. Lund and Rysavy) published an article entitled "A New Percutaneous Vena Cava Filter" (the "Cragg II paper"). [FN38] The Cragg II paper describes the design and manufacture of a nitinol vena cava filter, the method used to place such a filter into the vena cava veins of eleven dogs, the ability of the filters to capture clots, and how long the filters stayed open. For two of the eleven dogs in the study, "the original placement of the filters was not optimal. These filters were withdrawn into the catheter and successfully repositioned." (June 7, 2002 Grant Aff., Ex. H at 602 .) The Cragg II paper identified several advantages associated with use of the nitinol spiral filter versus other filters, including the fact that "it can be withdrawn and repositioned easily." (Id. at 603.)

FN38. Andrew Cragg, et al., "A New Percutaneous Vena Cava Filter," 141 Am. J. of Roentgenology 601-04 (Sept.1983) (attached as Ex. H to the June 7, 2002 Aff. of Celeste Grant).

***31** BSC has identified Andrew Cragg, M.D., Gunnar Lund, M.D., and Joseph Rysavy as witnesses who will testify regarding their work with nitinol in 1982 and 1983, work disclosed in the two articles described above. Medtronic moves for an order excluding any testimony from these witnesses

on the grounds that it is not admissible to prove that either the Cragg II paper or the filters themselves anticipate the claims of the patents-in-suit pursuant to 35 U.S.C. § 102(a).

BSC responds that its claims of patent invalidity are not restricted to a theory of anticipation by prior publication under § 102(a). According to BSC, testimony from the authors of the Cragg II paper is relevant and admissible with respect to numerous theories of invalidity. BSC asserts that, in addition to anticipation by prior publication, it also claims that the patents-in-suit are invalid on the grounds that (1) the nitinol vena cava filter experiments performed by Cragg, et al., and described in the Cragg II paper, are a "prior public use" under § 102(a) such that the inventions of the patents-in-suits were "known or used by others in this country ... before the invention thereof by [Jervis]"; (2) the nitinol vena cava filter experiments performed by Cragg, et al., are a "prior invention" under § 102(g); and (3) the nitinol vena cava filter experiments performed by Cragg, et al., and described in the Cragg II paper, are one element of prior art that can and should be factored into an obviousness analysis under § 103. The Court evaluates the admissibility of the Cragg II authors' testimony under each theory of invalidity. [FN39]

> FN39. Medtronic also objects that Cragg, Lund, and Rysavy cannot testify because they were not disclosed pursuant to Rule 26(a). In BSC's initial disclosures, it identified both employees and third persons whom it believed had information pertaining to the claims described in the pleadings. Under the category of third persons, BSC identified every author of every article listed in the "Other Publications" section of the patents-in-suit. Among those publications was the first paper in 1983 by Cragg, et al., regarding nitinol aortic stents. The Court finds no merit in Medtronic's objection.

1. Anticipation by prior publication

Section 102(a) provides that a person shall be entitled to a patent unless "the invention was ... described in a printed publication in this or a foreign country before the invention thereof by the applicant for patent." The Federal Circuit has stated that in order to invalidate a patent through anticipation by a prior publication, that publication "normally needs to disclose each and every limitation of the claim. However a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it ." Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1347 (Fed.Cir.1999). Whether an element of the claimed invention is inherent in the prior art reference is a question of fact. Id. at 1346.

When the prior art reference is silent about an asserted characteristic, the party asserting anticipation may resort to extrinsic evidence to establish that the characteristic is inherent in the reference. Continental Can Co. USA, Inc., v. Monsanto Co., 948 F.2d 1264, 1268 (Fed.Cir.1991). "The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed.Cir.1991). The concept of an "inherent" anticipation "accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of invention, albeit not known to judges ." Continental Can Co., 948 F.2d at 1269.

***32** Medtronic argues that BSC cannot rely on extrinsic evidence--namely, the testimony of the authors--to establish the existence of stress-induced martensite in the vena cava filters, an element of the claimed invention that is not expressly disclosed in the Cragg II paper. Medtronic further argues that the authors of the Cragg II paper are not competent to educate the jury as to what the Cragg II paper meant to persons of ordinary skill in the art; they themselves are not such persons. [FN40]

> FN40. BSC has submitted a proposed jury instruction stating that a "person of ordinary skill in the art" is "a mechanical engineer with one or more graduate degrees and with training and expertise in the use of materials, especially metal alloys."

BSC responds that it seeks to call Cragg, Lund, and Rysavy to "explain" the Cragg II paper. Relying on Continental Can and Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316 (Fed.Cir.2001), BSC argues that "recourse to extrinsic evidence is proper to determine whether a feature, while not explicitly discussed, is necessarily present in a reference." That statement of the law,

however, is ultimately inaccurate through omission. BSC has left off the second half of the Federal Circuit's requirement for extrinsic evidence, which "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill." Continental Can Co., 948 F.2d at 1268 (emphasis added), quoted in In re Robertson, 169 F.3d 743, 745 (Fed.Cir.1999).

None of the authors has been presented as being a person possessing "ordinary skill in the art." That is, none of the authors appears to be a mechanical engineer with one or more graduate degrees and with training and expertise in the use of materials, especially metal alloys. Therefore, none of the Cragg II authors can educate the jury or the Court as to what the paper meant to a mechanical engineer with one or more graduate degrees and with training and expertise in the use of materials, especially metal alloys. [FN41]

> FN41. Therefore, several of the cases cited by BSC are distinguishable. See Continental Can Co., 948 F.2d at 1266-69 (author of patent allegedly anticipating patent-in-suit for a plastic bottle having ribbed bottom structure was skilled in the art of plastic molding processes); Scripps Clinic & Research Found., 927 F.2d at 1577 (author of dissertation that allegedly anticipated patent-in-suit for ultra-purification of a blood clotting factor using monoclonal antibodies was scientist engaged in research on isolation and purification of the same blood-clotting factor).

The Federal Circuit has allowed testimony from a prior art author where that testimony "merely explained what [the author] meant when using the phrase '[Baxter] Travenol's commercial, two blood bag container.' " In re Baxter Travenol Labs., 952 F.2d 388, 390-91 (Fed.Cir.1991). The court of appeals observed in that case, however, that its ultimate decision on anticipation did not depend solely upon the author's testimony:

> [D]epositions and declarations of skilled workers and Baxter's own admissions were used to identify what materials Baxter's commercial bags contained at the time of the [allegedly anticipating] document, thereby explaining what the phrase '[Baxter] Travenol's commercial, two blood bag container' would have meant to one skilled in the art.

Id. at 390 (emphasis added). BSC has identified no terms or phrases in the Cragg II article that require such explanatory testimony. Rather, BSC states that it will call the authors to testify about "the details underlying the paper which, although perhaps not explicitly mentioned, will prove that stress-induced martensite is inherent in the device and procedures described in the Cragg II paper." (Defs.' Mem. Opp'n to Mot. in Limine Excluding Test. of Authors at 6.)

***33** Testimony about "details" (i.e., facts) not set out in the Cragg II paper sounds to the undersigned like filling in gaps of substantive information, not simply explaining "what the reference meant to persons of ordinary skill in the field of the invention." Scripps Clinic & Research Found., 927 F.2d at 1576. BSC has failed to demonstrate that the Cragg II authors will testify about "common knowledge of technologists [that] is not recorded in the reference." Continental Can Co., 948 F.2d at 1269. While the authors' testimony may be relevant to other theories of invalidity, as discussed below, it does not fall within the scope of permissible extrinsic evidence for a claim of invalidity anticipation by prior publication. The Court concludes that Medtronic is entitled to a limiting instruction informing the jury that testimony from the Cragg, Lund, and Rysavy cannot be considered in deciding whether the limitation of stress-induced martensite is inherently present in the Cragg II paper.

2. Prior invention

Under 35 U.S.C. § 102(g), a person is not entitled to a patent if "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." The "prior invention" restriction identifies two events that are significant for determining priority: "conception" [FN42] and "reduction to practice."

> FN42. "Conception is the touchstone of inventorship, the completion of the mental part of the invention." Sewall v. Walters, 21 F.3d 411, 415 (Fed.Cir.1994). As the Federal Circuit recently defined it, [c]onception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice. A conception

> must encompass all limitations of the claimed invention, and is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. Brown v. Barbacid, 276 F.3d 1327, 1335-36 (Fed.Cir.2002) (internal citations and quotation marks omitted).
>
> In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102(g).

Medtronic contends that Cragg, Rysavy, and Lund cannot testify to their "prior invention" of what is claimed in the patents-in-suit because "uncorroborated oral testimony by alleged prior inventors is never enough to satisfy the clear and convincing evidence standard under ... section 102(g)." (Medtronic's Mem. Supp. Mot. to Exclude Oral Testimony of Cragg II Authors at 5.) Medtronic contends that "[t]he Cragg II article itself cannot corroborate the oral testimony of the authors because it is silent as to the existence or use of stress-induced martensite, the key claim element that BSC seeks to prove is present." (Id.) Furthermore, Medtronic argues, there is no other tangible or documentary evidence to corroborate the authors' testimony. Medtronic asserts that any laboratory notebooks or samples of nitinol wire kept by one or more of the authors cannot be introduced into evidence because those items were never produced during discovery. (Id. at 6.) As for photographs or slides of the experiments, Medtronic argues that they are not admissible because Dr. Cragg could not identify them at his deposition.

BSC responds that extrinsic evidence is admissible to prove prior invention under § 102(g) and that the typical corroboration requirement does not apply in this case because the witnesses are wholly disinterested pecuniarily in the result of the case. [FN43] In addition, BSC contends that if corroboration is necessary, it exists in the form of the articles and numerous slides and photographs taken that depict various aspects of the procedures described in the Cragg II paper.

FN43. In light of the Court's analysis of the Finnigan and Thomson S.A. cases, infra in this section, the Court need not resolve the question of whether Cragg, Lund, and Rysavy are pecuniarily disinterested in the outcome of this case. Nevertheless, the Court would find it hard to conclude that Cragg is a wholly disinterested witness, given that BSC has agreed to pay him a substantial sum over three years for work in connection with this case and has purchased from him rights to other medical devices he has designed.

***34** Before addressing the corroboration requirement, a threshold issue must be resolved: "Who is/are the alleged prior inventor(s)?" BSC says it must be allowed "to prove that the inventions described in the claims in suit were first made by Cragg and his colleagues." (Defs.' Mem. Opp'n to Mot. in Limine to Exclude Test. of Authors at 9 (emphasis added).) The "prior inventors" must therefore be all of the authors of the two 1983 articles, including Cragg, Lund, and Rysavy.

Assuming that all three proposed author-witnesses are "prior inventors," the next consideration is whether there is evidence available to corroborate their testimony.

> Corroborating evidence may take many forms. Reliable evidence of corroboration preferably comes in the form of physical records that were made contemporaneously with the alleged prior invention. See Sandt Tech., Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350-51, 60 USPQ2d 1091, 1094 (Fed.Cir.2001) ("Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated." (citing Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1373, 47 USPQ2d 1363, 1367 (Fed.Cir.1998))). Circumstantial evidence about the inventive process may also corroborate.

Trovan, Ltd. v. Sokymat S.A., No. 01-1360, 2002 WL 1766003 at *8 (Fed.Cir. Aug.1, 2002). In this case, there are obviously the articles themselves. Medtronic asserts that the Cragg II paper cannot corroborate the inventors' testimony because stress-induced martensite is not expressly disclosed in it. If the only evidence of the limitation missing in the Cragg II paper came from the inventors' testimony, the claim of invalidity would ultimately fail for lack of clear and convincing evidence. See Finnigan

Corp. v. United States Int'l Trade Comm'n, 180 F.3d 1354, 1364-66, 1370 (Fed.Cir.1999), discussed in Juicy Whip, Inc. v. Orange Bang, Inc., 292 F.3d 728, 742-43 (Fed.Cir.2002). In addition to the article, however, there are also slides and photographs, apparently taken contemporaneously with the experiments. Assuming one of the three authors can authenticate the pictures and lay an adequate foundation for their admission, they, too, may substantiate the authors' testimony. [FN44] Finally, expert testimony may corroborate the author's testimony. See Finnigan, 180 F.3d at 1368 (discussing record before trial court supporting finding of anticipation in Thomson S.A. v. Quixote Corp., 166 F.3d 1172, 1174 (Fed.Cir.1999)). As discussed above, the Court has denied Medtronic's motion to exclude Dr. Bhattacharya's expert testimony regarding the formation of stress-induced martensite in the nitinol vena cava filters.

> FN44. The fact that Cragg could not identify them at his deposition is not dispositive of their admissibility.

Corroborating evidence exists for Cragg, Lund, and Rysavy's testimony. The sufficiency of that evidence shall be evaluated at trial under a "rule of reason" analysis, under which "[a]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the [alleged] inventor's story may be reached." Trovan Ltd., 299 F.3d 1292, 2002 WL 1766003 at *8 (quoting Price v. Symsek, 988 F.2d 1187, 1195 (Fed.Cir.1993) (emphasis omitted)). The Court concludes that Medtronic has failed to establish that the author-witnesses must be precluded from testifying on the grounds that there is no corroborating evidence for their testimony of prior inventorship.

***35** As for the underlying issue of whether corroboration is necessary, the Court observes that the parties have focused their arguments around two 1999 Federal Circuit opinions. Medtronic relies predominantly on Finnigan Corp., which held that, with respect to any invalidity claim under § 102, uncorroborated testimony concerning invalidating activities is insufficient, as a matter of law, to "surmount the hurdle that the clear and convincing evidence standard imposes on proving patent invalidity." 180 F.3d at 1370. BSC cites Thomson S.A., decided by a different panel of the Federal Circuit five months prior to Finnigan and holding that uncorroborated testimony from a non-party inventor can alone satisfy the clear and convincing evidence standard for purposes of § 102(g) where the "prior inventor" has no vested interest in the outcome of the litigation. Specifically, the court in Thomson held that

> corroboration is required only when the testifying inventor is asserting a claim of derivation or priority of his or her invention and is a named party, an employee of or assignor to a named party, or otherwise is in a position where he or she stands to directly and substantially gain by his or her invention being found to have priority over the patent claims at issue.

166 F.3d at 1176 (emphasis added).

Having reviewed the Finnigan and Thomson opinions, the Court concludes that they are irreconcilable. Despite the express holding in Thompson, quoted above, the panel in Finnigan held that "the need for corroboration exists regardless whether the party testifying concerning the invalidating activity is interested in the outcome of the litigation (e.g., because that party is the accused infringer) or is uninterested but testifying on behalf of an interested party." Finnigan, 180 F.3d at 1367. The Finnigan panel distinguished Thomson on the grounds that "the facts in Thomson did not present the question of the necessity of corroboration vel non, but rather the sufficiency of the corroborating evidence, a distinct inquiry involving an assessment of the totality of the circumstances, including consideration of 'the interest of the corroborating witness in the subject matter of the suit.' " Id. at 1368-69. In short, the Finnigan court concluded that the holding in Thomson was dicta, and the case does not "stand for the proposition that only an interested witness's testimony requires corroboration." Id. at 1369.

From the reasoning and holding of Finnigan, it appears that the necessity of corroboration arises not from "the level of interest of the testifying witness, but rather because of doubt that testimonial evidence alone in the special context of proving patent invalidity can meet the clear and convincing evidentiary standard to invalidate a patent." Finnigan, 180 F.3d at 1168. Regardless of Cragg, Lund, and Rysavy's interest in this lawsuit, corroboration of their testimony concerning prior invention will be necessary. The sufficiency of BSC's proposed corroboration will be evaluated at

trial.

3. Prior public use

***36** In addition to anticipation by prior publication, BSC argues that the patents-in-suit are invalid because "the invention was known or used by others in this country ... before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). Specifically, BSC contends that the authors' work with the nitinol vena cava filters was an invalidating public use. Medtronic complains that BSC never disclosed a "prior use" defense under § 102(a) and has belatedly and improperly crafted it immediately before trial. Medtronic has not, however, presented any evidence suggesting that BSC refused to disclose its "prior use" defense in discovery. Simply because BSC did not move for summary judgment on the "prior public use" bar of § 102(a) does not preclude it from asserting that defense at trial.

As discussed in the previous subsection, Finnigan made the corroboration requirement applicable to all oral evidence regarding invalidating activities under § 102; that is, the corroboration requirement applies to more than just the "prior invention" bar of § 102(g). For the reasons set forth in subsection 2, supra, the sufficiency of the evidence corroborating the alleged invalidating prior use shall be evaluated at trial in light of all pertinent evidence.

4. Obviousness

Section 103 provides that

> [a] patent may not be obtained, though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

BSC contends that its obviousness defense is based on the totality of the prior art at the relevant time, including the Cragg II paper and the other work that the authors did with nitinol. Medtronic objects to BSC's proposed obviousness argument on the grounds that it varies from the bases for obviousness BSC presented on summary judgment. BSC replies that it identified the Cragg II paper in its § 282 disclosure. Medtronic has cited no authority that would preclude BSC from changing the combination of prior art references that allegedly render the patents-in-suit obvious.

At the motion hearing, counsel for Medtronic further asserted that the Cragg II authors cannot provide testimony establishing that a person of ordinary skill in the art would have found it obvious, at the time the invention was made, to modify or combine the prior art references BSC has now identified, including the Cragg II paper, and there is no other expert testimony to establish a suggestion or motivation to combine. (Hrg. Tr. at 92.) BSC responded that expert testimony is not necessary to establish invalidity due to obviousness.

To establish invalidity on the grounds of obviousness, the relevant inquiry is what a hypothetical person of ordinary skill in the art "would have gleaned from the cited references at the time that the patent application leading to the [patents-in-suit were] filed." Amazon.com. Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1364 (Fed.Cir.2001). Put another way, "there ... must be evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.' " Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375 (Fed.Cir.2000) (quoting In re Rouffet, 149 F.3d 1350, 1357 (Fed.Cir.1998)), cert. denied, 532 U.S. 974 (2001).

***37** While the Court has not found authority holding that expert testimony must in every instance be presented in order to establish obviousness, cases from the Federal Circuit certainly demonstrate that expert testimony is generally presented to establish that theory of invalidity. See, e.g., General Elec. Co. v. Nintendo Co., Ltd., 179 F.3d 1350, 1363 (Fed.Cir.1999) (finding genuine issues of material fact on question of obviousness where each party presented expert testimony as to whether a particular limitation was known in the art at the time of the filing of the patent-in-suit and as to background knowledge held by one skilled in the art at the time of that filing); Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1472 (Fed.Cir.1997) (sustaining jury finding of suggestion to combine prior art references where alleged infringer's experts

"testified in detail about the teachings of each reference and the motivations that one skilled in the art might have to combine the various references."); Hoover Group, Inc. v. Custom Metalcraft, Inc., 66 F.3d 299, 303 (Fed.Cir.1995) (affirming district court's conclusion that alleged infringer "failed to present any testimony supporting" obviousness where testimony of infringers' experts as to skill in the art was presented to establish their qualification as experts and "not to establish the level of ordinary skill in this field or to provide a basis for deciding what a person of ordinary skill would have deemed to be obvious at the time the invention was made.").

The Court concludes that the Cragg II paper authors may testify as fact witnesses to those things as to which they have first-hand knowledge. Fed.R.Evid. 602. Whether that testimony, together with whatever other testimony is presented by Defendants at trial to establish invalidity of the patents-in-suit for obviousness, can withstand a Rule 50 motion is an inquiry for another day.

B. Plaintiff's Motion to Exclude Testimony that Would Vary the Court's Claim Construction

Before analyzing Medtronic's motion, it is important to review the procedural history of the Court's claim construction. After receiving briefing from the parties, the Court held a Markman hearing on August 9, 2001. On August 20, 2001, the parties simultaneously submitted proposed findings of fact, conclusions of law, and orders on claim construction. Both parties proposed constructions for the terms "stress-induced martensite," "shape memory alloy," and "pseudoelastic shape memory alloy." Both parties also submitted proposed constructions for additional terms or phrases. Medtronic asked to have four additional phrases construed. BSC asked for the construction of four "universal terms" and two longer "claim phrases" (one from the independent claim 1 of each patent).

The Court issued a Memorandum Opinion and Order on claim construction on August 31, 2001, in which it construed the terms "stress-induced martensite," "shape memory alloy," and "pscudoclastic shape memory alloy." The Court also stated in a footnote that BSC had asked the Court to construe additional claims but, "[a]fter reviewing BSC's proposed claim construction ... it appears that the only substantive difference in BSC's proposed claim construction is its addition of the phrase 'without cooling' to stress-induced martensite. The Court, therefore, will not address the claim constructions proposed by BSC." (Aug. 31, 2001, Mem. Op. & Order at 15 n. 4.) The case proceeded to cross-motions for summary judgment. In connection with its motion, BSC did not assert that additional terms needed to be construed before the Court could enter a summary judgment of non-infringement.

***38** In their trial brief, BSC asserts that the claims have been only partially construed and, once they are fully construed, it will be evident that the RADIUSTM stent does not infringe any of the asserted claims. (Defs.' Tr. Br. at 4.) Medtronic responds that this Court found, correctly, that no further claim terms required construction in light of the Court's definition of "stress-induced martensite," relying on footnote 4 of the August 31, 2001 Memorandum Opinion and Order, quoted above. (Pl.'s Reply to Defs.' Tr. Br. at 1, 4 n. 3.) Plaintiff moves for an order precluding BSC from introducing any evidence that would rebut or challenge this Court's claim construction.

BSC contends that the Court's "early construction" of three of the disputed terms of the patent is

> important, but not set in stone. The court's ultimate duty is to correctly construe the patent claims before instructing the jury. Live testimony at trial regarding the patent and technology will assist this Court to confirm whether its prior construction was correct and may well generate other terms about which the jury will need instruction.

(Defs.' Mem. Opp'n to Mot. in Limine Re: Court's Claim Construction at 1-2.) BSC intends to present evidence at trial about "the background of the patent, the meaning of terms in the patent, and technology related to the patent." (Id. at 3.) Counsel for BSC stated at the motion hearing that it intends to introduce the file history and specification into evidence so that the jury can determine what Jervis said his inventions were. While stating that BSC accepts the court's claim construction "so far," counsel indicated that terms still remain to be construed and that it is impossible for a court to construe every term of every claim in a technical patent such as ones in-suit. (Hrg. Tr. at 60-61.) BSC contends that it is entitled to argue to the jury,

"When you folks in the jury apply this claim to the product, keep in mind here's what [the inventor] said. Here's what he said his invention was." (Id. at 64.)

> It is beyond dispute that
> [a] determination of infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted ... [Second,] the properly construed claims are compared to the allegedly infringing device." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454, 46 USPQ2d 1169, 1172 (Fed.Cir.1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71, 34 USPQ2d 1321, 1322 (Fed.Cir.1995) (en banc), aff'd, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).... Step two, comparison of the claim to the accused device, requires a determination that every claim limitation or its equivalent be found in the accused device. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). Those determinations are questions of fact. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353, 48 USPQ2d 1674, 1676 (Fed.Cir.1998).

*39 Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1370 (Fed.Cir.2002); see also Finnigan Corp., 180 F.3d at 1362. The party alleging infringement bears the burden of proving that each and every limitation set forth in a patent claim is found in the accused product. CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1161 (Fed.Cir.1997). The Federal Circuit has recently emphasized that it is the claims of the patent that are central to the infringement analysis:

> Both the Supreme Court and this Court have adhered to the fundamental principle that claims define the scope of patent protection.... See, e.g., Aro Mfg. v. Convertible Top Replacement Co., 365 U.S. 336, 339, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961) ("[T]he claims made in the patent are the sole measure of the grant...."); Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 419, 28 S.Ct. 748, 52 L.Ed. 1122 (1908) ("[T]he claims measure the invention."); Atl. Thermoplastics Co. v. Faytex Corp., 974 F.2d 1299, 1300, 24 USPQ2d 1138, 1139-40 (Fed.Cir.1992) ("The claims alone define the patent right."); SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121, 227 U.S.P.Q. 577, 585 (Fed.Cir.1985) ("It is the claims that measure the invention."). The claims thus give notice of the scope of patent protection. See, e.g., Mahn v. Harwood, 112 U.S. 354, 361, 5 S.Ct. 174, 28 L.Ed. 665 (1884) ("The public is notified and informed by the most solemn act on the part of the patentee, that his claim to invention is for such and such an element or combination, and for nothing more.").
> * * * *
> Moreover, the law of infringement compares the accused product with the claims as construed by the court. Infringement, either literally or under the doctrine of equivalents, does not arise by comparing the accused product "with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee." SRI Int'l, 775 F.2d at 1121.

Johnson & Johnston Assocs. Inc. v. R.E. Service Co., Inc., 285 F.3d 1046, 1052 (Fed.Cir.2002) (emphasis added).

At the motion in limine hearing, counsel for BSC argued that the jury is to apply the claims-at-issue to the accused product "in light of the specification and file history." (Hrg. Tr. at 67.) According to BSC, an accused infringer can defend against a claim of infringement by arguing to the jury that its accused device does not infringe a claim of the patent because, based on the specification and the file history, the inventor "really" invented something other than what the trial court has construed the claims to mean. The Court finds no authority, nor has BSC cited any, for such a proposition. [FN45] Claim construction is the stage of the infringement analysis at which the Court decides what the inventor invented.

> FN45. Virtually all of the cases the Court has found discussing a jury's consideration of a specification involve the alleged infringement of a means-plus-function or step-plus-function claim under 35 U.S.C. § 112 ¶ 6. "Whether an accused device or method infringes a claim with a § 112, ¶ 6 limitation, i.e., whether it performs the identical function with the same structure, materials, or acts described in the specification or an equivalent thereof, is a question of fact." IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1430 (Fed.Cir.2000). The patents-in-suit are not drafted as means-plus-function patents. The Court has found only one other Federal Circuit opinion

> mentioning a jury's consideration of the specification or prosecution history in the context of deciding infringement. CVI/Beta Ventures, Inc. involved an appeal from the denial of an alleged infringer's motion for judgment as a matter of law. The trial, held in late 1994 prior to the Markman decision, had been conducted as follows: The magistrate declined to instruct the jury on the meaning of the claims. Rather, he only gave the jury general instructions relating to claim construction. The magistrate informed the jury that it should look to the ordinary meanings of the words used in the claims and that it should consider the patent specifications and the prosecution histories. The magistrate also instructed the jury that it should construe the claims as they would be construed by one of ordinary skill in the art, unless the specifications indicated that the inventors intended other meanings. 112 F.3d at 1151. Whatever the law was in 1994, it is clear now that claim construction is a matter for the court, not the jury. CVI/Beta Ventures cannot support BSC's position.

With respect to the three terms that were construed in the August 2001 Order, the parties have had their opportunity to advance their interpretations of those terms in light of the intrinsic evidence, and the Court has done what Markman requires of it. The Court's interpretation of those terms are not "preliminary" or "tentative ." Regardless of the approach employed by another judge of this Court, the undersigned finds no reason in this case to defer the task of claim construction until the close of the evidence.

***40** The Court has sua sponte reconsidered the assessment made in footnote 4 of the August 31, 2001, Markman opinion and concludes it is incorrect. BSC's argument that terms relating to stress-induced martensite must be construed to include the phrase "without cooling" or "isothermally" (which the Court rejected) is not the only argument distinguishing BSC's proposed claim interpretations from those of Medtronic. The following summarizes the parties' positions on the terms remaining at issue:

Term/phrase	Medtronic's requested construction	Defendants' requested construction
deformed	none	A change in shape
deformed configuration	none	The configuration of the shape memory alloy when it is in its stress-induced martensitic state
deformed shape	none	The shape of the shape memory alloy when it is in its stress-induced martensitic state
reversible stress-induced martensite	stress-induced martensite that can revert to an austenitic phase	none
... the element being restrained in a deformed configuration, the restraining means stressing the element thereby inducing stress-induced martensite in the alloy ('957 patent, claim 1)	(asking only for construction of the highlighted text): Stress-induced martensite that forms in a shape memory alloy due to the presence of stress created by a restraint	the restraint preventing the deformed alloy from regaining its original unstressed configuration, the restraint applying a deforming stress without cooling, resulting in deformation of the alloy and transformation of the austenite to stress-induced martensite
a restraint holding the shape memory alloy element in a deformed configuration ... the deformation occurring through the formation of stress-induced martensite ('378 patent,	(asking only for construction of the highlighted text) alteration of the shape or crystalline structure of a shape memory alloy that coincides with the presence of stress-induced martensite	the restraint holding the shape memory alloy ("SMA") in a deformed configuration, the deformed SMA being obtained by the application of a deforming stress to austenite (without cooling) which deforms the alloy and transforms the austenite to stress-induced martensite

claim 1)

displays stress-induced martensite behavior at body temperature	(adding the words in italics to the phrase) stress-induced martensite that will convert to austenite at body temperature upon removal of restraint	a shape memory alloy originally in austenite that is subjected to a deforming stress (without cooling), resulting in deformation of the alloy and transformation of the austenite to stress-induced martensite, and, upon removal of that deforming stress: (a) if the temperature is above A F , it regains its original shape by transforming back from stress-induced martensite to austenite; or (b) if the temperature is between A S and A F , it partially regains its original shape by partially transforming back form stress-induced martensite to austenite; or (c) if the temperature is below A S , it partially or fully regains its shape only if the alloy is subsequently heated to a temperature above A S or A F , respectively, thereby causing a portion or all of the stress-induced martensite to transform back to austenite, respectively.

*41 Since the Markman hearing, BSC has identified no other terms that it believes require construction because they are either technical or ambiguous. Thus, the Court finds no merit in BSC's assertion that evidence relevant to claim construction should be presented to the jury because other, unspecified and unknown claim terms may need to be construed before the infringement claim can be submitted. Furthermore, contrary to the assertion of BSC's counsel, the Court concludes that it is indeed possible to construe each and every claim that Medtronic has alleged BSC has infringed. The Court's claim construction will follow in a separate Memorandum Opinion and Order.

Accordingly, the Court will grant in part Medtronic's motion and preclude BSC from arguing to the jury how the claims of the patents-in-suit should be construed. Nothing in this ruling shall prevent BSC from presenting evidence that is properly relevant to issues other than claim construction.

C. Plaintiff's Motion to Exclude Opinions of Counsel and for a Jury Instruction on Drawing an Adverse Inference [FN46]

> FN46. Medtronic identified three opinions from counsel in its opening memorandum. Two can be addressed here. The first, from Fish and Richardson, is no longer at issue, as BSC is withdrawing it from evidence. Medtronic acknowledges the issue is moot. The second is a letter from the Vidas, Arrett law firm dated May 26, 1998, stating that the RADIUSTM stent does not infringe the '957 patent and other patents not in suit. Only in Medtronic's reply does it become clear that the grounds for excluding the letter are hearsay, estoppel, and, under Federal Rule of Evidence 106, that it has been so heavily redacted as to be misleading. The Court will address those objections in connection with the parties' objections to exhibits.

Frank Grillo, a vice-president at BSC, testified at BSC's 30(b)(6) deposition that Boston Scientific had received an oral validity opinion from the law firm of Kenyon & Kenyon at the time it was negotiating the purchase of the Raychem bundle--the summer of 1996. When counsel for Medtronic asked about the substance of that opinion, Grillo was instructed not to answer on the grounds of attorney-client privilege. Furthermore, Medtronic complains, BSC has refused to disclose communications between Boston Scientific and the Kenyon & Kenyon law firm in response to discovery requests on the grounds of attorney-client privilege.

On the BSC privileged documents log, BSC identified several letters and memoranda "related to Jervis patent evaluation" that date from between September 20, 1996 and December 11, 1997. [FN47] (June 7, 2002 Grant Aff. Ex. DD, Nos. 16-20 & 24; July 1, 2002 Grant Aff., Ex. F, Nos. 38, 41, 42 & 44-47.) With two exceptions, Charles R. Brainard, Esq., and/or Paul A. Bondor, Esq., appear as either direct or carbon copy recipients of the letters and memoranda. The first exception is a February 21, 1997 facsimile transmission from Paul Bondor to Dave Cavanaugh, copy to Charles Brainard, which is described as a "confidential communication related to Jervis patent evaluation--prior art." (July 1, 2002 Grant Aff. Ex. F No. 42.) The second exception is a December 17, 1997 memorandum from Charles Brainard, Esq., to Charles Brainard, Esq., described as a "confidential document related to analysis of Jervis patents"; that document evidently came into BSC's possession at some point. (June 7, 2002 Grant Aff. Ex. DD, No. 24.) In its responses to interrogatories, BSC identified Charles Brainard as being an attorney with Kenyon & Kenyon and one who conducted or helped conduct an "investigation, search, test, analysis or evaluation" related to infringement and/or the validity or enforceability of one or more of the patents-in-suit. (Id. Ex. EE at 9.) Medtronic asserts, upon information and belief, that Paul Bondor was also an attorney at Kenyon & Kenyon.

> FN47. All of these document post-date Medtronic's purchase of the Raychem bundle in August 1996.

*42 BSC now contends that Grillo was mistaken in his 30(b)(6) deposition testimony. Grillo now avers, over eighteen months after the deposition, that, since testifying at the 30(b)(6) deposition, [FN48] he

> FN48. BSC apparently did not correct the deposition transcript pursuant to Federal Rule of Civil Procedure 30(e). The Court need not decide at this time whether Grillo will be permitted to testify at trial in a manner inconsistent with his deposition testimony.

> spoke[ ] to other BSC employees who have refreshed my recollection on this subject. I am not sure of the source of my original confusion, but I am presently unaware of any opinion concerning the validity of the Raychem Patents, which was offered by Kenyon & Kenyon or any other law firm prior to the time that BSC decided to launch the Radius stent system.

(June 19, 2002 Aff. of Francis Grillo ¶ 3.) At the hearing on the motions in limine, counsel for BSC represented that BSC received a written opinion letter from Kenyon & Kenyon dated in 1999. [FN49] (Hrg. Tr. at 81.) A document appears on the BSC privilege log as a memorandum from Charles R. Brainard, Esq. to Mark Casey, Esq. and Luke Dohmen, Esq., dated May 23, 1999, which is described as a "confidential communication between attorneys related to patent opinion of Jervis patents." (June 7, 2002 Grant Aff., Ex. DD, No. 27.) BSC observes that this written opinion comes long after it had made the decision to market the RADIUSTM stent system. BSC first offered the RADIUSTM stent system for sale in the United States in July 1998.

> FN49. That document was identified on BSC's privilege log as a "memorandum." Counsel for BSC indicated at the hearing that the document is on Kenyon & Kenyon letterhead, addressed in letter form to recipients at BSC, and begins "Dear ____."

Medtronic moves for (a) an order precluding BSC from introducing evidence regarding the Kenyon & Kenyon opinion and (b) an instruction at trial advising the jury that, due to BSC's refusal to disclose the opinion from Kenyon & Kenyon, they may draw an adverse inference that the opinion was unfavorable to BSC. BSC responds that it does not intend to introduce the 1999 Kenyon & Kenyon opinion letter at trial; therefore an order precluding it from doing so is unnecessary. Furthermore, BSC argues, Medtronic is not entitled to an adverse inference instruction because the 1999 Kenyon & Kenyon opinion letter post-dates the Defendants' decision to launch the accused product and is, therefore, irrelevant to the issue of willfulness.

"[W]illful infringement arises upon deliberate disregard for the property rights of the patentee. Thus the focus is generally on whether the infringer exercised due care to avoid infringement, usually by seeking the advice of competent and objective counsel, and receiving exculpatory advice." Vulcan Eng'g Co., Inc. v. Fata Aluminium, Inc., 278 F.3d 1366, 1378 (Fed.Cir.2002), pets. for cert. filed (May 6 & June 5, 2002); see also Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 944 (Fed.Cir.1992). Because the duty of due care typically "includes seeking and obtaining competent legal advice before engaging in activity that may result in infringement," the Federal Circuit has held that "when an infringer refuses to produce an exculpatory opinion of counsel in response to a charge of willful infringement, an inference may be drawn that either no opinion was obtained or, if an opinion was obtained, it was unfavorable." Electro Med. Sys., S.A. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1056 (Fed.Cir.1994). The importance of an opinion of counsel as a defense to willful infringement places the accused infringer in something of a dilemma. The accused infringer "must either (1) rely on such advise as a defense and thereby waive the attorney-client privilege as to the entire subject area or (2) relinquish the advice-of-counsel defense." Belmont Textile Mach. Co. v. Superba, S.A., 48 F.Supp.2d 521, 523 (W.D.N.C.1999).

***43** The record presented on Medtronic's motion establishes the existence of two categories of documents associated with the Kenyon & Kenyon law firm. The first is the series of letters and memoranda from late 1996 and 1997 that relate to an "evaluation" of the Jervis patents, including an assessment of prior art. The second category consists of the May 23, 1999 letter relating to a "patent opinion of Jervis patents." The Court considers whether an adverse inference may flow from BSC's assertion of the attorney-client privilege for either category.

1. Communications from 1996 and 1997

The written communications in 1996 and 1997 between BSC and attorneys Brainard and Bondor, including Bondor's February 1997 facsimile and Brainard's December 1997 memorandum, pre-date not only the market launch of the RADIUSTM stent system in July 1998 but also the letter from the Vidas, Arrett law firm in May 1998, [FN50] on which BSC would like to rely for an opinion-of-counsel defense. Grillo's recent affidavit does not lay to rest the question of whether Kenyon & Kenyon ever provided an oral opinion to BSC prior

to the launch of the RADIUSTM stent. He has averred, in his individual capacity, that he is "presently unaware of any opinion concerning the validity of the Raychem Patents, which was offered by Kenyon & Kenyon or any other law firm prior to the time that BSC decided to launch the Radius stent system." Such an averment is not necessarily inconsistent with the existence of an opinion from Kenyon & Kenyon.

FN50. This letter is labeled on the BSC privileged document log as a "memorandum" from Richard A. Arrett, Esq., to Luke Dohmen, Esq. and is described as a "confidential communication between attorneys related to patent opinion of Jervis patents." (June 7, 2000 Grant Aff. Ex. DD, No. 25.)

From the record, it certainly appears that Kenyon & Kenyon both provided and received correspondence and memoranda during 1996 and 1997 regarding the Jervis patents. Where an alleged infringer declines to introduce an opinion of counsel at trial, "a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer's desire to initiate or continue its use of the patentee's invention." Fromson v. Western Litho Plate & Supply Co., 853 F.2d 1568, 1572-73 (Fed.Cir.1988): see also Electro Med. Sys., S.A., 34 F.3d at 1056; Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 133 F.Supp.2d 843, 862 (E.D.Va.2001); Lucent Techs., Inc. v. Newbridge Networks Corp., 168 F.Supp.2d 269, 275 (D.Del.2001). Assertion of the attorney-client privilege with respect to infringement and validity opinions of counsel, therefore, may support the drawing of adverse inferences. L.A. Gear, Inc. v. Thorn McAn Shoe Co., 988 F.2d 1117, 1126 (Fed.Cir.1993); cf. Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 21 F.Supp.2d 366, 377-78 (S.D.N.Y.1998) (drawing adverse inference on willfulness where only legal opinion that infringer was willing to present had been formulated by someone with a stake in lawsuit's outcome and contained numerous errors and where record revealed existence of various other opinions by other counsel, all of which were shielded behind attorney-client privilege), aff'd, 231 F.3d 1339 (Fed.Cir.2000).

***44** The Court concludes that Medtronic is entitled to an instruction that the jury may infer, from BSC's failure to disclose any opinion regarding the patents-in-suit obtained from Kenyon & Kenyon prior to May 23, 1998, either that no opinion was obtained or that, if it were obtained, it was contrary to BSC's desire to initiate or continue its use of the invention disclosed in the patents-in-suit.

2. The 1999 memorandum from Brainard

BSC argues that the May 1999 memorandum from Brainard cannot be relevant to a willfulness inquiry because it post-dates the Defendants' decision to market the RADIUSTM stent. BSC relies on Critikon, Inc., v. Becton Dickinson Vascular Access, Inc. ., 120 F.3d 1253 (Fed.Cir.1997), which reversed a trial court's finding, in a bench trial, that the infringer's actions were not willful. Assessing the determination that the infringer's actions were reasonable, the Federal Circuit criticized the trial court for relying on opinions of counsel obtained after marketing of the accused device had begun. For purposes of deciding willfulness, the district court could "only rely on those four opinions received prior to marketing" of the infringer's accused device. Critikon, Inc., 120 F.3d at 1259.

None of the cases Medtronic cites in its reply has held that the contents of opinion-of-counsel letters received after infringement has begun are relevant to a willfulness determination. One case holds that all "patent opinion letters that the defendants received before the lawsuit was commenced relating to the patents at issue" are discoverable. THK America, Inc. v. NSK Co. Ltd., 157 F.R.D. 637, 648 (N.D.Ill.1993). Whether information is discoverable is not the same question, however, as whether it is admissible at trial. Another case states that the timing of an advice-of-counsel letter--that is, the defendant's delay in obtaining one-was relevant to an assessment of willfulness. National Presto Indus. v. West Bend Co., 76 F.3d 1185, 1193 (Fed.Cir.1996). The third case again involved timing; an opinion of counsel letter, "though credible, came too late to be reasonably relied upon because '[i]t was not rendered until MEC had been infringing the ['765] patent for almost twenty months.' " American Med. Sys., Inc. v. Medical Eng'g Corp., 6 F.3d 1523, 1531 (Fed.Cir.1993). Based on Critikon, Inc., the Court concludes that Medtronic is not entitled to an adverse inference

instruction based upon the May 1999 letter from Brainard.

D. BSC's Motion to Exclude Potential Character Evidence

BSC has learned that counsel for Medtronic has asserted, during an opening argument in another lawsuit in this district, that its products "save a life every twelve seconds." BSC seeks to exclude what it describes as evidence of "good corporate character" such as the statistic about life-saving products on the grounds that such evidence is irrelevant to any issue in this patent infringement suit. Medtronic responds that evidence of the amount of a reasonable royalty rate under a licensing agreement depends in part upon the value of the products covered by those patents. Medtronic thus argues that a patent covering medical devices that play a substantial role in saving lives can command a substantial royalty rate.

***45** Medtronic cites no authority for its proposition that the fact that a patent holder is a company that manufactures and sells medical devices that save human lives is relevant to a damages inquiry under Georgia Pacific. Nor has Medtronic established that Robert Goldscheider, its damages expert, has ever factored into his "reasonable royalty" analysis--either in his original expert report or his supplemental expert report--the fact that Medtronic manufactures and sells devices that save several human lives per minute. Furthermore, although Medtronic asserts generally that information about the life-saving capabilities of its products is important to establish "context" for the issues to be presented to the jury, it fails to identify what issues require "context" and how the proposed evidence of lives-saved-per-minute would establish such "context." The Court concludes that evidence of "good corporate character," such as a comment about how many lives are saved per minute by Medtronic products, is irrelevant to any issue that the jury will be asked to decide and, hence, not admissible under Rules 401 and 402 of the Federal Rules of Evidence. The Court will grant BSC's motion.

Conclusion

Based on the foregoing, and all of the files, records and proceedings herein, IT IS ORDERED that

1. Defendants' Motion in Limine to Exclude Evidence Relating To the Price of, Offers for, or Value of the "Raychem Bundle" (Doc. No. 187-1) is GRANTED IN PART; Medtronic shall not present evidence, including opinion or inferential testimony, regarding the value of the patents-in-suit relative to the total amount paid for the "Raychem bundle."

2. Defendants' Motion in Limine to Exclude Testimony of Medtronic's Damages Expert Goldscheider (Doc. No. 187-2) is GRANTED; Goldscheider shall not testify, in the form of opinion or inferential testimony, regarding "convoyed sales" or the value of the patents-in-suit relative to the entire "Raychem bundle."

3. Defendants' Motion in Limine to Exclude Evidence of Royalty Rates Negotiated in the Settlement of Other Litigation (Doc. No. 187-3) is GRANTED.

4. Defendants' Motion in Limine to Exclude Evidence Relating to the Defendants' Lawsuit or Day-to-day Relationship with Medinol, Ltd. (Doc. No. 187-4) is GRANTED; nothing in this ruling, however, precludes Medtronic from presenting expert testimony regarding the impact of the Medinol agreement on the profitability of the RADIUSTM stent for Boston Scientific.

5. Defendants' Motion in Limine to Exclude Testimony under Rule 702 of Dr. Lagoudas (Doc. No. 187-5) is GRANTED; Medtronic shall not present evidence, including but not limited to testimony from Dr. Lagoudas, regarding the measurements and experiments conducted on actual specimen RADIUSTM stents.

6. Defendants' Motion in Limine to Exclude Evidence of Medtronic's Good Corporate Character (Doc. No. 187-6) is GRANTED.

7. Medtronic's Motion in Limine to Exclude Testimony of the Defendants' Experts, Dr. Bhattacharya and Dr. Muskivitch (Doc. No. 200) is GRANTED IN PART AND DENIED IN PART; Dr. Bhattacharya shall not testify regarding the non-infringement of the patents-in-suit by the RADIUSTM stent, and Dr. Muskivitch is precluded from testifying.

*46 8. Medtronic's Motion in Limine to Exclude Opinions of Counsel Offered by Defendant and For an Adverse Inference (Doc. No. 202) is GRANTED IN PART AND DENIED IN PART; Medtronic is entitled to an adverse inference instruction arising from the Defendants' failure to disclose communications from 1996 and 1997 with the Kenyon & Kenyon law firm, but is not entitled to such an instruction with respect to the 1999 opinion letter. The Court shall reserve ruling on the opinion letter from the Vidas, Arrett law firm.

9. Medtronic's Motion in Limine to Preclude Defendants' Damages Expert from Testifying to Boston Scientific's Belief that the RADIUSTM Stent was a Non-infringing Alternative (Doc. No. 204) is GRANTED.

10. Medtronic's Motion in Limine to Exclude Evidence Rebutting or Challenging the Court's Claim Construction (Doc. No. 206) is GRANTED; BSC is precluded from arguing to the jury how the claims of the patents-in-suit should be construed. Nothing in this ruling shall prevent BSC from presenting evidence that is properly relevant to issues other than claim construction.

11. Medtronic's Motion in Limine to Exclude Testimony from the Authors of the Cragg II Paper (Doc. No. 208) is DENIED; the Court concludes, however, that Medtronic is entitled to an instruction that said testimony is admissible for a limited purpose.

12. Medtronic's Motion in Limine to Exclude Expert Testimony from the Defendants' Employees (Doc. No. 210) is GRANTED IN PART AND DENIED IN PART; Brian Brown shall not offer testimony in the form of opinion or inference regarding whether austenite forms or stress-induced martensite is present in the RADIUSTM stent. The Defendants shall submit--by Monday, August 19, 2002--a detailed written offer of proof describing the facts to which each employee-witness proposes to testify and that witness's competence to testify as to those facts.

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